

US3432229 (Prod: Brigham and Womens Hospital)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:22:31

All time stamps listed in this document are displayed in GMT

US3432229

**Form: Participant Creation**

**Generated On: 26 Nov 2020 09:22:31**

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[Participant ID](#)

US3432229

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

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US3432229

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 21 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 09:22:31

|                                           |                                                                                                                                                                            |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy)                  | (b) (6) 1996                                                                                                                                                               |
| Age                                       | 24                                                                                                                                                                         |
| Age Units                                 | YEARS                                                                                                                                                                      |
| Age (Derived)                             | 24                                                                                                                                                                         |
| 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 09:22:31

|                                                 |                                              |
|-------------------------------------------------|----------------------------------------------|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 21 AUG 2020                                  |
| Month and Year of Informed Consent (derived)    | AUG 2020                                     |
| Year of Informed Consent (derived)              | 2020                                         |
| Protocol Version                                | Amendment 1 <input type="radio"/>            |
|                                                 | Amendment 2 <input checked="" type="radio"/> |
|                                                 | Amendment 3 <input type="radio"/>            |
|                                                 | Amendment 4 <input type="radio"/>            |
|                                                 | Amendment 5 <input type="radio"/>            |
| Was participant enrolled in the study?          | Yes <input checked="" type="radio"/>         |
|                                                 | No <input type="radio"/>                     |
| If No, indicate reason for screen fail          | Withdrew Consent <input type="radio"/>       |
|                                                 | Inclusion/Exclusion <input type="radio"/>    |
|                                                 | Cohort Full <input type="radio"/>            |
|                                                 | Other <input type="radio"/>                  |
| If reason for screen fail is Other, specify     |                                              |
| Was this participant screened previously?       | Yes <input type="radio"/>                    |
|                                                 | No <input checked="" type="radio"/>          |
| If Yes, previous participant number             |                                              |
| Enrollment Trigger                              | 1                                            |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:22:31

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:22:31

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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 09:22:31

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | ADHD                                                             |
| Start date (dd MMM yyyy)                                | UN UNK 2016                                                      |
| 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 2016                                                         |
| Start Year (derived)                                    | 2016                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:22:31

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | MOOD DISORDER                                                    |
| Start date (dd MMM yyyy)                                | UN UNK 2009                                                      |
| 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 2009                                                         |
| Start Year (derived)                                    | 2009                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | ASTHMA                                                           |
| Start date (dd MMM yyyy)                                | UN UNK 1998                                                      |
| 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 1998                                                         |
| Start Year (derived)                                    | 1998                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:22:31

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | ORTHOSTATIC PRE-SYNCOPI                                          |
| Start date (dd MMM yyyy)                          | UN UNK 2009                                                      |
| 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 2009                                                         |
| Start Year (derived)                              | 2009                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:22:31

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | DYSMENORRHEA                                                     |
| Start date (dd MMM yyyy)                          | UN UNK 2008                                                      |
| 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 2008                                                         |
| Start Year (derived)                              | 2008                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

|                                           |                                      |
|-------------------------------------------|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|                                           | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 21 AUG 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 10:32 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 21 AUG 2020 10:32                    |
| Height ( <i>xxx.x</i> )                   | 159.1 cm                             |
| Weight ( <i>xxx.x</i> )                   | 067.2 kg                             |
| BMI ( <i>xxx.x</i> )                      | 26.54782 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 09:22:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 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 09:22:31

Date of assessment (*dd MMM yyyy*) 21 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 09:22:31

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| Was the pregnancy test performed?   | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of test ( <i>dd MMM yyyy</i> ) | 21 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 09:22:31

#### Occupational Risk

|                                                                                                                                                         |                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| <b>Healthcare workers</b> (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)                                            | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" 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 checked="" type="radio"/> |
|                                                                                                                                                         | No <input 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 09:22:31

|                                                                                                                                        |       |
|----------------------------------------------------------------------------------------------------------------------------------------|-------|
| <b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)                                 | True  |
| <b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes) | False |
| <b>Resides in a single family home</b> (i.e., detached housing)                                                                        | 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 09:22:31

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 21 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 09:22:31

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 144547

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

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

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

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

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

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

Liver Disease Yes ☐   
 No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐   
 No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 21 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 10:32 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 21 AUG 2020 10:32                                                                                      |
| Temperature (xxx.x)                 | 36.5 C                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 077 beats/min                                                                                          |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 10 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 121 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 069 mmHg                                                                                               |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 21 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 13:26 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 21 AUG 2020 13:26                                                                                      |
| Temperature (xxx.x)                 | 37.1 C                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 073 beats/min                                                                                          |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 14 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 124 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 075 mmHg                                                                                               |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

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 09:22:31

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 09:22:31

|                                                                                                              |                                                                    |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| 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)                                                                   | 21 AUG 2020                                                        |
| What was the treatment time? (00:00-23:59)                                                                   | 12:56 (24 HR)                                                      |
| Treatment Date and Time (derived)                                                                            | 21 AUG 2020 12:56                                                  |
| 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 09:22:31

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

21 AUG 2020

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

11:00 (24 HR)

Collection date and time (derived)

21 AUG 2020 11:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:22:31

|                                        |                           |                                          |                                    |
|----------------------------------------|---------------------------|------------------------------------------|------------------------------------|
| Collection date ( <i>dd MMM yyyy</i> ) |                           |                                          | 21 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                       | 11:05                                    | 21 AUG 2020 11:05                  |
| Nasopharyngeal Swab 2                  | No                        |                                          |                                    |

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp 21 AUG 2020 13:31

PC Open Date & Time 21 AUG 2020 13:16

PC Close Date & Time 21 AUG 2020 15:46

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp 21 AUG 2020 16:50

PC Open Date & Time 21 AUG 2020 16:41

PC Close Date & Time 22 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**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 <b>TEMPERATURE</b> taken?                             | Yes <input checked="" type="radio"/> |
|                                                           | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F               | 98.3 °F                              |
| Was any <b>MEDICATION TAKEN today for pain or fever</b> ? | Yes <input checked="" type="radio"/> |
|                                                           | No <input type="radio"/>             |

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

|                                                         |       |
|---------------------------------------------------------|-------|
| To <b>TREAT</b> pain or fever that has already occurred | True  |
| To <b>PREVENT</b> pain or fever from occurring          | False |

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 22 AUG 2020 18:40 |
| PC Open Date & Time  | 22 AUG 2020 12:00 |
| PC Close Date & Time | 23 AUG 2020 11:59 |



US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

|                                                           |                                      |
|-----------------------------------------------------------|--------------------------------------|
| Was <b>TEMPERATURE</b> taken?                             | Yes <input checked="" type="radio"/> |
|                                                           | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F               | 98.3 °F                              |
| Was any <b>MEDICATION TAKEN today for pain or fever</b> ? | Yes <input checked="" type="radio"/> |
|                                                           | No <input type="radio"/>             |

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

|                                                         |                   |
|---------------------------------------------------------|-------------------|
| To <b>TREAT</b> pain or fever that has already occurred | True              |
| To <b>PREVENT</b> pain or fever from occurring          | True              |
| PC Time Stamp                                           | 24 AUG 2020 10:48 |
| PC Open Date & Time                                     | 23 AUG 2020 12:00 |
| PC Close Date & Time                                    | 24 AUG 2020 11:59 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:22:31

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 22:40

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:22:31

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 22:43

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**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 <b>TEMPERATURE</b> taken?                             | Yes <input checked="" type="radio"/> |
|                                                           | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F               | 98.3 °F                              |
| Was any <b>MEDICATION TAKEN today for pain or fever</b> ? | Yes <input checked="" type="radio"/> |
|                                                           | No <input type="radio"/>             |

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

|                                                         |       |
|---------------------------------------------------------|-------|
| To <b>TREAT</b> pain or fever that has already occurred | True  |
| To <b>PREVENT</b> pain or fever from occurring          | False |

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 27 AUG 2020 07:55 |
| PC Open Date & Time  | 26 AUG 2020 12:00 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:22:31

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.3 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

27 AUG 2020 23:59

---

PC Open Date & Time

27 AUG 2020 12:00

---

PC Close Date & Time

28 AUG 2020 11:59

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US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

53

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

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

Yes ☒

No ☐

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

5

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 13:34

PC Open Date & Time

21 AUG 2020 13:16

PC Close Date & Time

21 AUG 2020 15:46

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**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

21 AUG 2020 16:52

PC Open Date & Time

21 AUG 2020 16:41

PC Close Date & Time

22 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**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

22 AUG 2020 18:40

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59



US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 10:48

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**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

24 AUG 2020 22:38

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**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

25 AUG 2020 22:43

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**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

27 AUG 2020 07:55

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**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

27 AUG 2020 23:59

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**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 ☐

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 21 AUG 2020 13:34 |
| PC Open Date & Time  | 21 AUG 2020 13:16 |
| PC Close Date & Time | 21 AUG 2020 15:46 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**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 ☐



US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 21 AUG 2020 16:51 |
| PC Open Date & Time  | 21 AUG 2020 16:41 |
| PC Close Date & Time | 22 AUG 2020 11:59 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 22 AUG 2020 18:41 |
| PC Open Date & Time          | 22 AUG 2020 12:00 |
| PC Close Date & Time         | 23 AUG 2020 11:59 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 24 AUG 2020 10:49 |
| PC Open Date & Time          | 23 AUG 2020 12:00 |
| PC Close Date & Time         | 24 AUG 2020 11:59 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**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 ☒

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 24 AUG 2020 22:38 |
| PC Open Date & Time          | 24 AUG 2020 12:00 |
| PC Close Date & Time         | 25 AUG 2020 11:59 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

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 ☒



US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 25 AUG 2020 22:44 |
| PC Open Date & Time          | 25 AUG 2020 12:00 |
| PC Close Date & Time         | 26 AUG 2020 11:59 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 27 AUG 2020 07:56 |
| PC Open Date & Time          | 26 AUG 2020 12:00 |
| PC Close Date & Time         | 27 AUG 2020 11:59 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

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

US3432229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

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

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3432229

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3432229

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3432229

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 18 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                                  |

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| 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)    | 18 SEP 2020                               |
| Time of assessment (00:00-23:59)    | 10:47 (24 HR)                             |
| Vital Signs Date and Time (derived) | 18 SEP 2020 10:47                         |
| Temperature (xxx.x)                 | 37.0 C                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |                                           |
| Pulse (xxx)                         | 74 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 14 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 113 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 68 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

|                                     |                                            |
|-------------------------------------|--------------------------------------------|
| Timepoint                           | Pre-Dose <input type="radio"/>             |
|                                     | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>       |
|                                     | No <input type="radio"/>                   |
| Date of assessment (dd MMM yyyy)    | 18 SEP 2020                                |
| Time of assessment (00:00-23:59)    | 11:44 (24 HR)                              |
| Vital Signs Date and Time (derived) | 18 SEP 2020 11:44                          |
| Temperature (xxx.x)                 | 36.5 C                                     |
| Route of measurement                | Oral <input type="radio"/>                 |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input checked="" type="radio"/>     |
| If Other, specify                   | IR                                         |
| Pulse (xxx)                         | 73 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)      | 61 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3432229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3432229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| Was the pregnancy test performed?   | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of test ( <i>dd MMM yyyy</i> ) | 18 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)  |                                           |



US3432229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

|                                                                                                              |                                                                    |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| 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)                                                                   | 18 SEP 2020                                                        |
| What was the treatment time? (00:00-23:59)                                                                   | 11:14 (24 HR)                                                      |
| Treatment Date and Time (derived)                                                                            | 18 SEP 2020 11:14                                                  |
| 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                                                      |

US3432229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 18 SEP 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 11:00 (24 HR)                        |
| Collection date and time (derived)     | 18 SEP 2020 11:00                    |

US3432229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:22:31

| Collection date (dd MMM yyyy) |                           |                                 | 18 SEP 2020                        |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 11:05                           | 18 SEP 2020 11:05                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3432229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**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

18 SEP 2020 11:45

PC Open Date & Time

18 SEP 2020 11:34

PC Close Date & Time

18 SEP 2020 14:04

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp 18 SEP 2020 20:50

PC Open Date & Time 18 SEP 2020 14:59

PC Close Date & Time 19 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**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 99.3 °F

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

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

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

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

PC Time Stamp 19 SEP 2020 12:54

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

|                                                           |                                      |
|-----------------------------------------------------------|--------------------------------------|
| Was <b>TEMPERATURE</b> taken?                             | Yes <input checked="" type="radio"/> |
|                                                           | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F               | 97.0 °F                              |
| Was any <b>MEDICATION TAKEN today for pain or fever</b> ? | Yes <input checked="" type="radio"/> |
|                                                           | No <input type="radio"/>             |

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

|                                                         |                   |
|---------------------------------------------------------|-------------------|
| To <b>TREAT</b> pain or fever that has already occurred | True              |
| To <b>PREVENT</b> pain or fever from occurring          | True              |
| PC Time Stamp                                           | 20 SEP 2020 17:07 |
| PC Open Date & Time                                     | 20 SEP 2020 12:00 |
| PC Close Date & Time                                    | 21 SEP 2020 11:59 |



US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

22 SEP 2020 00:00

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:22:31

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

23 SEP 2020 02:55

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**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 <b>TEMPERATURE</b> taken?                             | Yes <input checked="" type="radio"/> |
|                                                           | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F               | 98.2 °F                              |
| Was any <b>MEDICATION TAKEN today for pain or fever</b> ? | Yes <input checked="" type="radio"/> |
|                                                           | No <input type="radio"/>             |

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

|                                                         |       |
|---------------------------------------------------------|-------|
| To <b>TREAT</b> pain or fever that has already occurred | True  |
| To <b>PREVENT</b> pain or fever from occurring          | False |

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 23 SEP 2020 21:41 |
| PC Open Date & Time  | 23 SEP 2020 12:00 |
| PC Close Date & Time | 24 SEP 2020 11:59 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:22:31

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 23:59

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 11:46

PC Open Date & Time

18 SEP 2020 11:34

PC Close Date & Time

18 SEP 2020 14:04

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**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

18 SEP 2020 20:50

PC Open Date & Time

18 SEP 2020 14:59

PC Close Date & Time

19 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**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

19 SEP 2020 12:54

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 17:03

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59



US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**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

22 SEP 2020 00:00

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**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

23 SEP 2020 02:55

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**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

23 SEP 2020 21:41

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**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

24 SEP 2020 23:59

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**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 ☐

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 18 SEP 2020 11:46 |
| PC Open Date & Time  | 18 SEP 2020 11:34 |
| PC Close Date & Time | 18 SEP 2020 14:04 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**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 ☐

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 18 SEP 2020 20:51 |
| PC Open Date & Time  | 18 SEP 2020 14:59 |
| PC Close Date & Time | 19 SEP 2020 11:59 |



US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

|                      |                              |
|----------------------|------------------------------|
|                      | Yes <input type="checkbox"/> |
| PC Time stamp        | 19 SEP 2020 12:55            |
| PC Open Date & Time  | 19 SEP 2020 12:00            |
| PC Close Date & Time | 20 SEP 2020 11:59            |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 20 SEP 2020 17:03 |
| PC Open Date & Time          | 20 SEP 2020 12:00 |
| PC Close Date & Time         | 21 SEP 2020 11:59 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

|                      |                           |
|----------------------|---------------------------|
|                      | Yes <input type="radio"/> |
| PC Time stamp        | 22 SEP 2020 00:01         |
| PC Open Date & Time  | 21 SEP 2020 12:00         |
| PC Close Date & Time | 22 SEP 2020 11:59         |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 23 SEP 2020 02:56 |
| PC Open Date & Time          | 22 SEP 2020 12:00 |
| PC Close Date & Time         | 23 SEP 2020 11:59 |



US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

|                      |                           |
|----------------------|---------------------------|
|                      | Yes <input type="radio"/> |
| PC Time stamp        | 23 SEP 2020 21:42         |
| PC Open Date & Time  | 23 SEP 2020 12:00         |
| PC Close Date & Time | 24 SEP 2020 11:59         |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 24 SEP 2020 23:59 |
| PC Open Date & Time          | 24 SEP 2020 12:00 |
| PC Close Date & Time         | 25 SEP 2020 11:59 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

DAY 8

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp 26 SEP 2020 00:00

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 09:22:31

|                                                                                                         |                                                                  |
|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                        | DAY 8                                                            |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input type="radio"/><br>Yes <input checked="" type="radio"/> |
| PC Time stamp                                                                                           | 26 SEP 2020 00:00                                                |
| PC Open Date & Time                                                                                     | 25 SEP 2020 12:00                                                |
| PC Close Date & Time                                                                                    | 26 SEP 2020 11:59                                                |

US3432229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

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

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3432229

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3432229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3432229

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3432229

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

|                                                                 |                                       |
|-----------------------------------------------------------------|---------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>  |
|                                                                 | No <input type="radio"/>              |
| Visit date (dd MMM yyyy)                                        | 16 OCT 2020                           |
| Was visit performed at the participant's home or at the clinic? | Home <input checked="" type="radio"/> |
|                                                                 | Clinic <input type="radio"/>          |
| Folder OID                                                      | VISIT3                                |

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

|                                           |                                       |
|-------------------------------------------|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|                                           | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 16 OCT 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 11:24 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 16 OCT 2020 11:24                     |
| Temperature ( <i>xxx.x</i> )              | 98.7 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|                                           | Axillary <input type="radio"/>        |
|                                           | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 86 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 16 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 104 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 58 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3432229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

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.*

US3432229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

11:39 (24 HR)

Collection date and time (derived)

16 OCT 2020 11:39



US3432229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

**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

23 OCT 2020 12:00:26

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 71                                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input checked="" type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <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 checked="" type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                                |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | False                                                                                                          |
| Chills                                                                                                                                                                          | False                                                                                                          |
| Cough                                                                                                                                                                           | False                                                                                                          |
| Shortness of breath                                                                                                                                                             | False                                                                                                          |
| Difficulty breathing                                                                                                                                                            | False                                                                                                          |
| Fatigue                                                                                                                                                                         | False                                                                                                          |
| Muscle aches                                                                                                                                                                    | False                                                                                                          |
| Body aches                                                                                                                                                                      | False                                                                                                          |
| Headache                                                                                                                                                                        | False                                                                                                          |
| New loss of taste                                                                                                                                                               | False                                                                                                          |
| New loss of smell                                                                                                                                                               | False                                                                                                          |
| Sore throat                                                                                                                                                                     | True                                                                                                           |
| Congestion                                                                                                                                                                      | False                                                                                                          |
| Runny nose                                                                                                                                                                      | False                                                                                                          |
| Nausea                                                                                                                                                                          | False                                                                                                          |
| Vomiting                                                                                                                                                                        | False                                                                                                          |
| Diarrhea                                                                                                                                                                        | False                                                                                                          |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input checked="" type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission                                                                                                                                                     | 31 OCT 2020 18:45:23                                                                                           |
| Patient Cloud Open Date & Time                                                                                                                                                  | 28 OCT 2020 00:01                                                                                              |
| v6.020 DTW (1102)                                                                                                                                                               | 122 of 1953                                                                                                    |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

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US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 78                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                  |
| Date and time of submission                                                                                                                                                     | 08 NOV 2020 11:59:17                                             |
| Patient Cloud Open Date & Time                                                                                                                                                  | 04 NOV 2020 00:01                                                |
| Patient Cloud Close Date & Time                                                                                                                                                 | 08 NOV 2020 23:59                                                |

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 89                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 117                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 124                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 138                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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="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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 180                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                            |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 201                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 208                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 236                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 243                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 271                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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="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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 327                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 348                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 362                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 369                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 425                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

**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 ☐ 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 ☐

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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="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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 474                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 481                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 488                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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06 JAN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

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09 JAN 2022 00:01

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13 JAN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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27 JAN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 530                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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="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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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17 FEB 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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24 FEB 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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="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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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03 MAR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

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10 MAR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

**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 ☐



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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17 MAR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

**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 ☐

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

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24 MAR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

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27 MAR 2022 00:01

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31 MAR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

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03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 600                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



US3432229

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

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**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

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10 APR 2022 00:01

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14 APR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

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**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 614                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐ 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 ☐



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

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14 JUL 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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21 JUL 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 705                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

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28 JUL 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

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04 AUG 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

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**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

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07 AUG 2022 00:01

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11 AUG 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

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14 AUG 2022 00:01

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18 AUG 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

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25 AUG 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 761                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| TIMEPOINT                                                                                                                                                                       | DAY 789                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

| 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"/>                                               |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3432229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

CALLED PT. 10NOV2020 A 10:08,  
11NOV2020 AT 10:00, 12NOV2020  
AT 10:17, AMD 16NOV2020 AT  
13:52 AND 18:34. LEFT VMS AT  
ALL CALLS BUT NO CONTACT  
MADE.

US3432229

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432229

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:22:31

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

US3432229

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

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

**Generated On: 26 Nov 2020 09:22:31**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3432229

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:22:31

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           |                                                                                                                                                                  |
| Adverse event                                                  | TRANSIENT<br>GASTROINTESTINAL ILLNESS                                                                                                                            |
| Was this a medically-attended AE?                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 04 SEP 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 05 SEP 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input checked="" type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | False                                                                                                                                                            |
| Hospital Admission Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Hospital Discharge Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>                                                                           |
| Number of Days in ICU                                          |                                                                                                                                                                  |
| v6.020 DTW (1102)                                              |                                                                                                                                                                  |
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Folder: Adverse Events

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



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Folder: Adverse Events

Form: Adverse Events (2)

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|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           |                                                                                                                                                                  |
| Adverse event                                                  | SORE THROAT                                                                                                                                                      |
| Was this a medically-attended AE?                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 10 SEP 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 10 SEP 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input checked="" type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | False                                                                                                                                                            |
| Hospital Admission Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Hospital Discharge Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>                                                                           |
| Number of Days in ICU                                          |                                                                                                                                                                  |
| Persistent or significant disability or incapacity             | False                                                                                                                                                            |

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Form: Adverse Events (2)

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

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Folder: Adverse Events

Form: Adverse Events (3)

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|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US078-2020-MRNA-1273-P30<br>1000007                                                                                                                          |
| Adverse event                                                  | SELF- INJURIOUS BEHAVIOR                                                                                                                                         |
| Was this a medically-attended AE?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 17 OCT 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 30 OCT 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input checked="" type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | True                                                                                                                                                             |
| Hospital Admission Date (dd MMM yyyy)                          | 24 OCT 2020                                                                                                                                                      |
| Hospital Discharge Date (dd MMM yyyy)                          | 30 OCT 2020                                                                                                                                                      |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/><br>Unknown <input type="radio"/>                                                                |
| Number of Days in ICU                                          |                                                                                                                                                                  |
| v6.020 DTW (1102)                                              | 346 of 1953                                                                                                                                                      |

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Form: Adverse Events (3)

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

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Folder: Adverse Events

Form: Adverse Events (3)

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PARTICIPANT PRESENTED TO THE ED ON 17OCT2020 FOR SELF-INJURIOUS BEHAVIOR. HAS HISTORY OF PSYCHIATRY HOSPITALIZATION ( LAST IN 2017 FOR SUICIDAL IDEATION). CURRENT EPISODE IS THOUGHT TO BE AN EXACERBATION OF TRAUMA THEY EXPERIENCED. STAYED IN ED 17-18 OCT. AND WAS TRANSFERRED TO A COMMUNITY CRISIS STABILIZATION UNIT. TRIED TO CALL PARTICIPANT TODAY, NO ANSWER. WILL FOLLOW UP.

24OCT20 - PT RE-CONSULTED IN ED FOR SELF-INJURIOUS BEHAVIOR. SYMPTOMATOLOGY AND ASSESSMENT ARE SIMILAR TO PREVIOUS ED VISIT ON 17OCT2020. BECAUSE OF RECENT FAILURE OF CCS LEVEL OF CARE, PT IS HOSPITALIZED FOR CURRENT EPISODE. ADMITTED THIS MORNING.

---

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

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US3432229

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

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

**Generated On: 26 Nov 2020 09:22:31**

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

Yes ☒

No ☐

---

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | VYVANSE                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | ADHD                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose per administration        | 40                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN                       | UNK 2016                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | WELLBUTRIN                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | MOOD DISORDER                                                                                                                                                                                                                                                                                                                                                                                                            |
| Dose per administration              | 450                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | SYMBICORT                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | ASTHMA                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration        | 2                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input checked="" type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input checked="" type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                                       |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Respiratory (Inhalation) | <input checked="" type="radio"/> |
|                                                    | Intralesional            | <input type="radio"/>            |
|                                                    | Intraperitoneal          | <input type="radio"/>            |
|                                                    | Nasal                    | <input type="radio"/>            |
|                                                    | Vaginal                  | <input type="radio"/>            |
|                                                    | Rectal                   | <input type="radio"/>            |
|                                                    | Intravenous              | <input type="radio"/>            |
|                                                    | Intravenous Bolus        | <input type="radio"/>            |
|                                                    | Intravenous Drip         | <input type="radio"/>            |
|                                                    | Other                    | <input type="radio"/>            |
| <hr/>                                              |                          |                                  |
| If route of administration is Other, specify <hr/> |                          |                                  |
| Start date (dd MMM yyyy)                           | UN FEB 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) <hr/>       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| <hr/>                                              |                          |                                  |
| Separate Dosage Number (derived)                   | 2                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|                                                    | 803                      | <input type="radio"/>            |
|                                                    | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | FLOVENT                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | ASTHMA                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration        | 2                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input checked="" type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input checked="" type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                                       |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

|                                                |                          |                                  |
|------------------------------------------------|--------------------------|----------------------------------|
|                                                | Respiratory (Inhalation) | <input checked="" type="radio"/> |
|                                                | Intralesional            | <input type="radio"/>            |
|                                                | Intraperitoneal          | <input type="radio"/>            |
|                                                | Nasal                    | <input type="radio"/>            |
|                                                | Vaginal                  | <input type="radio"/>            |
|                                                | Rectal                   | <input type="radio"/>            |
|                                                | Intravenous              | <input type="radio"/>            |
|                                                | Intravenous Bolus        | <input type="radio"/>            |
|                                                | Intravenous Drip         | <input type="radio"/>            |
|                                                | Other                    | <input type="radio"/>            |
| <hr/>                                          |                          |                                  |
| If route of administration is Other, specify   |                          |                                  |
| Start date (dd MMM yyyy)                       | UN JUN 2019              |                                  |
| Start date completely unknown                  | False                    |                                  |
| Ongoing?                                       | Yes                      | <input type="radio"/>            |
|                                                | No                       | <input checked="" type="radio"/> |
| <hr/>                                          |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy)         |                          | UN JUN 2020                      |
| Was this medication taken for solicited event? | Yes                      | <input type="radio"/>            |
|                                                | No                       | <input checked="" type="radio"/> |
| <hr/>                                          |                          |                                  |
| Separate Dosage Number (derived)               | 2                        |                                  |
| Interval Dosage Unit Number (derived)          | 1                        |                                  |
| Interval Dosage Definition (derived)           | 802                      | <input type="radio"/>            |
|                                                | 803                      | <input type="radio"/>            |
|                                                | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | ALBUTEROL                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | ASTHMA                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration              | 2                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose unit                            | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input checked="" type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                                       |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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|                                                    |                                      |                                     |
|----------------------------------------------------|--------------------------------------|-------------------------------------|
|                                                    | Respiratory (Inhalation)             | <input checked="" type="radio"/>    |
|                                                    | Intralesional                        | <input type="radio"/>               |
|                                                    | Intraperitoneal                      | <input type="radio"/>               |
|                                                    | Nasal                                | <input type="radio"/>               |
|                                                    | Vaginal                              | <input type="radio"/>               |
|                                                    | Rectal                               | <input type="radio"/>               |
|                                                    | Intravenous                          | <input type="radio"/>               |
|                                                    | Intravenous Bolus                    | <input type="radio"/>               |
|                                                    | Intravenous Drip                     | <input type="radio"/>               |
|                                                    | Other                                | <input type="radio"/>               |
| <hr/>                                              |                                      |                                     |
| If route of administration is Other, specify <hr/> |                                      |                                     |
| Start date (dd MMM yyyy)                           | 21 AUG 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) <hr/>       |                                      |                                     |
| Was this medication taken for solicited event?     | Yes <input type="radio"/>            | No <input checked="" type="radio"/> |
| <hr/>                                              |                                      |                                     |
| Separate Dosage Number (derived)                   | <hr/>                                |                                     |
| Interval Dosage Unit Number (derived)              | <hr/>                                |                                     |
| Interval Dosage Definition (derived)               | 802                                  | <input type="radio"/>               |
|                                                    | 803                                  | <input type="radio"/>               |
|                                                    | 804                                  | <input type="radio"/>               |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | TESTOSTERONE                                                                                                                                                                                                                                                                                                                                                                                                             |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | GENERAL HEALTH                                                                                                                                                                                                                                                                                                                                                                                                           |
| Dose per administration        | 40                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input checked="" type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input checked="" type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN NOV 2019              |                                  |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | <input type="text"/>     |                                  |
| Interval Dosage Unit Number (derived)                             | <input type="text"/>     |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | MELOXICAM                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | MENSTRUAL CRAMPS                                                                                                                                                                                                                                                                                                                                                                                                         |
| Dose per administration              | 14                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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|                                                                   |                                      |                                     |
|-------------------------------------------------------------------|--------------------------------------|-------------------------------------|
|                                                                   | Respiratory (Inhalation)             | <input type="checkbox"/>            |
|                                                                   | Intralesional                        | <input type="checkbox"/>            |
|                                                                   | Intraperitoneal                      | <input type="checkbox"/>            |
|                                                                   | Nasal                                | <input type="checkbox"/>            |
|                                                                   | Vaginal                              | <input type="checkbox"/>            |
|                                                                   | Rectal                               | <input type="checkbox"/>            |
|                                                                   | Intravenous                          | <input type="checkbox"/>            |
|                                                                   | Intravenous Bolus                    | <input type="checkbox"/>            |
|                                                                   | Intravenous Drip                     | <input type="checkbox"/>            |
|                                                                   | Other                                | <input type="checkbox"/>            |
| <hr/>                                                             |                                      |                                     |
| If route of administration is Other, specify <input type="text"/> |                                      |                                     |
| <hr/>                                                             |                                      |                                     |
| Start date (dd MMM yyyy)                                          | 22 AUG 2020                          |                                     |
| Start date completely unknown                                     | False                                |                                     |
| Ongoing?                                                          | Yes <input type="checkbox"/>         | No <input checked="" type="radio"/> |
| <hr/>                                                             |                                      |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            | 23 AUG 2020                          |                                     |
| Was this medication taken for solicited event?                    | Yes <input type="checkbox"/>         | No <input checked="" type="radio"/> |
| <hr/>                                                             |                                      |                                     |
| Separate Dosage Number (derived)                                  | 1                                    |                                     |
| Interval Dosage Unit Number (derived)                             | 1                                    |                                     |
| Interval Dosage Definition (derived)                              | 802 <input type="checkbox"/>         | 803 <input type="checkbox"/>        |
|                                                                   | 804 <input checked="" type="radio"/> |                                     |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | MELOXICAM                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | HEADACHE                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Dose per administration              | 14                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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|                                                                   |                                      |                          |
|-------------------------------------------------------------------|--------------------------------------|--------------------------|
|                                                                   | Respiratory (Inhalation)             | <input type="checkbox"/> |
|                                                                   | Intralesional                        | <input type="checkbox"/> |
|                                                                   | Intraperitoneal                      | <input type="checkbox"/> |
|                                                                   | Nasal                                | <input type="checkbox"/> |
|                                                                   | Vaginal                              | <input type="checkbox"/> |
|                                                                   | Rectal                               | <input type="checkbox"/> |
|                                                                   | Intravenous                          | <input type="checkbox"/> |
|                                                                   | Intravenous Bolus                    | <input type="checkbox"/> |
|                                                                   | Intravenous Drip                     | <input type="checkbox"/> |
|                                                                   | Other                                | <input type="checkbox"/> |
| <hr/>                                                             |                                      |                          |
| If route of administration is Other, specify <input type="text"/> |                                      |                          |
| <hr/>                                                             |                                      |                          |
| Start date (dd MMM yyyy)                                          | 27 AUG 2020                          |                          |
| Start date completely unknown                                     | False                                |                          |
| Ongoing?                                                          | Yes <input type="checkbox"/>         |                          |
|                                                                   | No <input checked="" type="radio"/>  |                          |
| <hr/>                                                             |                                      |                          |
| If not Ongoing, End date (dd MMM yyyy)                            | 27 AUG 2020                          |                          |
| Was this medication taken for solicited event?                    | Yes <input checked="" type="radio"/> |                          |
|                                                                   | No <input type="checkbox"/>          |                          |
| <hr/>                                                             |                                      |                          |
| Separate Dosage Number (derived)                                  | 1                                    |                          |
| Interval Dosage Unit Number (derived)                             | 1                                    |                          |
| Interval Dosage Definition (derived)                              | 802 <input type="checkbox"/>         |                          |
|                                                                   | 803 <input type="checkbox"/>         |                          |
|                                                                   | 804 <input checked="" type="radio"/> |                          |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | MELOXICAM                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HEADACHE                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Dose per administration        | 14                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input checked="" type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | SODIUM CHLORIDE                                                                                                                                                                                                                                                                                                                                                                                                          |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | ORTHOSTATIC PRE-SYNCOPI                                                                                                                                                                                                                                                                                                                                                                                                  |
| Dose per administration        | 1                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input checked="" type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          |                          | 25 AUG 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"/> |

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | TYLENOL                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | HEADACHES, PAIN AT<br>INJECTION SITE, MUSCLE<br>ACHES                                                                                                                                                                                                                                                                                                                                                                    |
| Dose per administration              | 1000                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input checked="" type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/>                                                                                                                                                                                                                                                                        |

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

|                                                    |                                         |                          |
|----------------------------------------------------|-----------------------------------------|--------------------------|
|                                                    | Intraocular                             | <input type="checkbox"/> |
|                                                    | Intramuscular                           | <input type="checkbox"/> |
|                                                    | Respiratory (Inhalation)                | <input type="checkbox"/> |
|                                                    | Intralesional                           | <input type="checkbox"/> |
|                                                    | Intraperitoneal                         | <input type="checkbox"/> |
|                                                    | Nasal                                   | <input type="checkbox"/> |
|                                                    | Vaginal                                 | <input type="checkbox"/> |
|                                                    | Rectal                                  | <input type="checkbox"/> |
|                                                    | Intravenous                             | <input type="checkbox"/> |
|                                                    | Intravenous Bolus                       | <input type="checkbox"/> |
|                                                    | Intravenous Drip                        | <input type="checkbox"/> |
|                                                    | Other                                   | <input type="checkbox"/> |
| If route of administration is Other, specify _____ |                                         |                          |
| Start date (dd MMM yyyy)                           | 19 SEP 2020                             |                          |
| Start date completely unknown                      | False                                   |                          |
| Ongoing?                                           | Yes <input type="checkbox"/>            |                          |
|                                                    | No <input checked="" type="checkbox"/>  |                          |
| If not Ongoing, End date (dd MMM yyyy)             | 20 SEP 2020                             |                          |
| Was this medication taken for solicited event?     | Yes <input checked="" type="checkbox"/> |                          |
|                                                    | No <input type="checkbox"/>             |                          |
| Separate Dosage Number (derived)                   | 3                                       |                          |
| Interval Dosage Unit Number (derived)              | 1                                       |                          |
| Interval Dosage Definition (derived)               | 802 <input type="checkbox"/>            |                          |
|                                                    | 803 <input type="checkbox"/>            |                          |
|                                                    | 804 <input checked="" type="checkbox"/> |                          |

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:22:31

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | IBUPROFEN                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | HEADACHES, PAIN AT<br>INJECTION SITE, MUSCLE<br>ACHES.                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration              | 600                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input checked="" type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/>                                                                                                                                                                                                                                                                        |

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:22:31

|                                                    |                                      |                          |
|----------------------------------------------------|--------------------------------------|--------------------------|
|                                                    | Intraocular                          | <input type="checkbox"/> |
|                                                    | Intramuscular                        | <input type="checkbox"/> |
|                                                    | Respiratory (Inhalation)             | <input type="checkbox"/> |
|                                                    | Intralesional                        | <input type="checkbox"/> |
|                                                    | Intraperitoneal                      | <input type="checkbox"/> |
|                                                    | Nasal                                | <input type="checkbox"/> |
|                                                    | Vaginal                              | <input type="checkbox"/> |
|                                                    | Rectal                               | <input type="checkbox"/> |
|                                                    | Intravenous                          | <input type="checkbox"/> |
|                                                    | Intravenous Bolus                    | <input type="checkbox"/> |
|                                                    | Intravenous Drip                     | <input type="checkbox"/> |
|                                                    | Other                                | <input type="checkbox"/> |
| If route of administration is Other, specify _____ |                                      |                          |
| Start date (dd MMM yyyy)                           | 19 SEP 2020                          |                          |
| Start date completely unknown                      | False                                |                          |
| Ongoing?                                           | Yes <input type="checkbox"/>         |                          |
|                                                    | No <input checked="" type="radio"/>  |                          |
| If not Ongoing, End date (dd MMM yyyy)             | 20 SEP 2020                          |                          |
| Was this medication taken for solicited event?     | Yes <input checked="" type="radio"/> |                          |
|                                                    | No <input type="checkbox"/>          |                          |
| Separate Dosage Number (derived)                   | 3                                    |                          |
| Interval Dosage Unit Number (derived)              | 1                                    |                          |
| Interval Dosage Definition (derived)               | 802 <input type="checkbox"/>         |                          |
|                                                    | 803 <input type="checkbox"/>         |                          |
|                                                    | 804 <input checked="" type="radio"/> |                          |

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:22:31

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | ZOFRAN                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | TRANSIENT<br>GASTROINTESTINAL ILLNESS                                                                                                                                                                                                                                                                                                                                                                                    |
| Dose per administration              | 4                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input checked="" type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/>                                                                                                                                                                                                                                   |

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:22:31

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Intramuscular            | <input type="radio"/>            |
|                                                    | Respiratory (Inhalation) | <input type="radio"/>            |
|                                                    | Intralesional            | <input type="radio"/>            |
|                                                    | Intraperitoneal          | <input type="radio"/>            |
|                                                    | Nasal                    | <input type="radio"/>            |
|                                                    | Vaginal                  | <input type="radio"/>            |
|                                                    | Rectal                   | <input type="radio"/>            |
|                                                    | Intravenous              | <input type="radio"/>            |
|                                                    | Intravenous Bolus        | <input type="radio"/>            |
|                                                    | Intravenous Drip         | <input type="radio"/>            |
|                                                    | Other                    | <input type="radio"/>            |
| <hr/>                                              |                          |                                  |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | 04 SEP 2020                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?                                           | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| <hr/>                                              |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 04 SEP 2020                      |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| <hr/>                                              |                          |                                  |
| Separate Dosage Number (derived)                   |                          | _____                            |
| Interval Dosage Unit Number (derived)              |                          | _____                            |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|                                                    | 803                      | <input type="radio"/>            |
|                                                    | 804                      | <input type="radio"/>            |



US3432229

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 09:22:31**

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

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

US3432229

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures**

**Generated On: 26 Nov 2020 09:22:31**

| Procedure/Surgery date ( <i>dd MMM<br/>yyyy</i> ) | Procedure/Surgery                           | Indication      | If indication is Other, specify |
|---------------------------------------------------|---------------------------------------------|-----------------|---------------------------------|
| 2 OCT 2020                                        | RTMS (TRANSCRANIAL<br>MAGNETIC STIMULATION) | Medical History |                                 |

US3432229

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:22:31

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3432229

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

|                                                                |                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                          | USA-US078-2020-MRNA-1273-P301000007                              |
| Serious                                                        | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death                                                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                      | LINDSEY                                                          |
| Investigator's Last Name                                       | BADEN                                                            |
| Site Address: Street                                           |                                                                  |
| Site Address: City                                             |                                                                  |
| Site Address: State                                            | MA                                                               |
| Site Address: Postal Code                                      |                                                                  |
| Investigator Country                                           | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                             | 3                                                                |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:22:31

|                                                                                                                                                                                               |                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US078-2020-MRNA-1273-P301000007                           |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | LINDSEY                                                       |
| Investigator's Last Name                                                                                                                                                                      | BADEN                                                         |
| Site Address: Street                                                                                                                                                                          |                                                               |
| Site Address: City                                                                                                                                                                            |                                                               |
| Site Address: State                                                                                                                                                                           | MA                                                            |
| Site Address: Postal Code                                                                                                                                                                     |                                                               |
| Investigator Country                                                                                                                                                                          | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 3                                                             |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 20/OCT/2020 19:09                                             |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True                                                          |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:22:31

|                                                                                                                                                                                               |                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US078-2020-MRNA-1273-P301000007                           |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | LINDSEY                                                       |
| Investigator's Last Name                                                                                                                                                                      | BADEN                                                         |
| Site Address: Street                                                                                                                                                                          |                                                               |
| Site Address: City                                                                                                                                                                            |                                                               |
| Site Address: State                                                                                                                                                                           | MA                                                            |
| Site Address: Postal Code                                                                                                                                                                     |                                                               |
| Investigator Country                                                                                                                                                                          | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 3                                                             |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 26/OCT/2020 16:01                                             |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True                                                          |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:22:31

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US078-2020-MRNA-1273-P301000007                              |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | LINDSEY                                                          |
| Investigator's Last Name                                                                                                                                                                      | BADEN                                                            |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           | MA                                                               |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 3                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 09/NOV/2020 07:37                                                |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True                                                             |



Audit

US3432229 (Prod: Brigham and Womens Hospital)

US3432229

**Form: Participant Creation**

**Generated On: 26 Nov 2020 09:22:31**

[Participant ID](#)

| Audit                    | User                                            | Time (GMT)           |
|--------------------------|-------------------------------------------------|----------------------|
| User entered 'US3432229' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 21 Aug 2020 14:39:29 |

US3432229

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:22:31**

[Was this visit performed?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 15:58:57 |

US3432229

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                                            | Time (GMT)           |
|----------------------------|-------------------------------------------------|----------------------|
| User entered '21 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 21 Aug 2020 14:39:30 |

US3432229

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                          | User                          | Time (GMT)           |
|--------------------------------|-------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 15:58:57 |

US3432229

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:22:31**

[Folder OID](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 21 Aug 2020 15:58:57 |

US3432229

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                                           | Time (GMT)           |
|----------------------------|------------------------------------------------|----------------------|
| User entered (b) (6) 1996' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 21 Aug 2020 14:39:31 |

US3432229

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:22:31**

[Age](#)

| Audit             | User                          | Time (GMT)           |
|-------------------|-------------------------------|----------------------|
| User entered '24' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:00:25 |



US3432229

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:22:31**

[Age Units](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 21 Aug 2020 16:00:25 |

US3432229

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:22:31**

[Age \(Derived\)](#)

| Audit             | User   | Time (GMT)           |
|-------------------|--------|----------------------|
| User entered '24' | System | 21 Aug 2020 16:01:09 |

US3432229

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:22:31**

[Sex](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| User entered 'Female (F)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:00:25 |

US3432229

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:22:31**

[Ethnicity](#)

| Audit                                                          | User               | Time (GMT)           |
|----------------------------------------------------------------|--------------------|----------------------|
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Xhoi Mitre (b) (4) | 21 Aug 2020 16:00:25 |

US3432229

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[White](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '1' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:00:25 |

US3432229

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:22:31**

[Black](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:00:25 |

US3432229

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:22:31**

[Asian](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:00:25 |

US3432229

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:22:31**

[American Indian or Alaska Native](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:00:25 |



US3432229

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:22:31**

[Native Hawaiian or other Pacific Islander](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:00:25 |

US3432229

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:22:31**

[Other](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:00:25 |

US3432229

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:22:31**

[If race is Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:00:25 |

US3432229

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:22:31**

[Unknown](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:00:25 |

US3432229

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:22:31**

[Not reported](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:00:25 |

US3432229

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:22:31**

[Date of Informed Consent \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '21 Aug 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:01:09 |

US3432229

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Aug 2020' | System | 21 Aug 2020 16:01:09 |

US3432229

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 21 Aug 2020 16:01:09 |



US3432229

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:22:31**

[Protocol Version](#)

| Audit                          | User                          | Time (GMT)           |
|--------------------------------|-------------------------------|----------------------|
| User entered 'Amendment 2 (2)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:01:09 |

US3432229

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:01:09 |

US3432229

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:01:09 |

US3432229

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:22:31**

If reason for screen fail is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:01:09 |

US3432229

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:22:31**

[Was this participant screened previously?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:01:09 |

US3432229

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:22:31**

[If Yes, previous participant number](#)

| Audit               | User                                           | Time (GMT)           |
|---------------------|------------------------------------------------|----------------------|
| User entered empty. | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 21 Aug 2020 14:39:30 |

US3432229

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:22:31**

[Enrollment Trigger](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 16:01:14 |

US3432229

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:01:14 |



US3432229

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 09:22:31**

[Were any significant conditions reported?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:44:20 |

US3432229

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

[Condition](#)

| Audit                                                                                                                                                                                                                                                    | User                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: ADHD - version MedDRA\23.0. | Coder Import (b) (4) | 21 Aug 2020 16:45:14 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                              | Coder Import (b) (4) | 21 Aug 2020 16:45:14 |
| Data point term sent to Coder                                                                                                                                                                                                                            | System               | 21 Aug 2020 16:44:50 |
| User entered 'ADHD'                                                                                                                                                                                                                                      | Xhoi Mitre (b) (4)   | 21 Aug 2020 16:44:37 |
|                                                                                                                                                                                                                                                          | (b) (4)              |                      |

US3432229

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'UN UNK 2016' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:44:37 |

US3432229

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:44:37 |

US3432229

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Condition ongoing at study entry](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:44:37 |

US3432229

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:44:37 |

US3432229

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Stop date completely unknown](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:44:37 |

US3432229

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2016' | System | 21 Aug 2020 16:44:37 |



US3432229

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2016' | System | 21 Aug 2020 16:44:37 |

US3432229

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 16:44:37 |

US3432229

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 16:44:37 |

US3432229

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:22:31

[Condition](#)

| Audit                                                                                                                                                                                       | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Psychiatric disorders, HLGT: Mood disorders and disturbances NEC, HLT: Mood disorders NEC, PT: Affective disorder, LLT: Mood disorder - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 16:46:16 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                | Coder Import (b) (4) | 21 Aug 2020 16:46:16 |
| Data point term sent to Coder                                                                                                                                                               | System               | 21 Aug 2020 16:45:52 |
| User entered 'Mood Disorder'                                                                                                                                                                | Xhoi Mitre (b) (4)   | 21 Aug 2020 16:44:55 |
|                                                                                                                                                                                             | (b) (4)              |                      |

US3432229

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'UN UNK 2009' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:44:55 |

US3432229

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:44:55 |

US3432229

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Condition ongoing at study entry](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:44:55 |

US3432229

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:44:55 |



US3432229

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Stop date completely unknown](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:44:55 |

US3432229

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2009' | System | 21 Aug 2020 16:44:55 |

US3432229

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2009' | System | 21 Aug 2020 16:44:55 |

US3432229

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 16:44:55 |

US3432229

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 16:44:55 |

US3432229

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

[Condition](#)

| Audit                                                                                                                                                                                                         | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 16:46:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                  | Coder Import (b) (4) | 21 Aug 2020 16:46:17 |
| Data point term sent to Coder                                                                                                                                                                                 | System               | 21 Aug 2020 16:45:54 |
| User entered 'Asthma'                                                                                                                                                                                         | Xhoi Mitre (b) (4)   | 21 Aug 2020 16:45:15 |
|                                                                                                                                                                                                               | (b) (4)              |                      |

US3432229

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'UN UNK 1998' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:45:15 |

US3432229

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:45:15 |



US3432229

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Condition ongoing at study entry](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:45:15 |

US3432229

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:45:15 |

US3432229

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Stop date completely unknown](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:45:15 |

US3432229

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1998' | System | 21 Aug 2020 16:45:15 |

US3432229

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1998' | System | 21 Aug 2020 16:45:15 |

US3432229

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 16:45:15 |

US3432229

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 16:45:15 |

US3432229

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:22:31

Condition

| Audit                                                                                                                                                                                                                                                  | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Presyncope, LLT: Pre-syncope - version MedDRA\23.0.                                                            | Coder Import (b) (4)<br>(b) (4)  | 23 Nov 2020 13:20:58 |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.                                                                                                                                                                   | Coder Import (b) (4)<br>(b) (4)  | 23 Nov 2020 13:20:58 |
| User closed query 'Per CDM: Per previous query response "Updated"; however, the update is not obvious please provide location of update such as log line number. Thank you. ' (Site from DM).                                                          | (b) (4), (b) (6)                 | 23 Nov 2020 07:49:12 |
| Query 'Per CDM: Per previous query response "Updated"; however, the update is not obvious please provide location of update such as log line number. Thank you. ' answered with 'updated within entry' (Site from DM).                                 | Julia Klopfer (b) (4)<br>(b) (4) | 10 Nov 2020 21:53:38 |
| User closed query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 06). ' (Site from DM).             | (b) (4), (b) (6)                 | 06 Nov 2020 08:05:28 |
| User opened query 'Per CDM: Per previous query response "Updated"; however, the update is not obvious please provide location of update such as log line number. Thank you. ' (Site from DM).                                                          | (b) (4), (b) (6)                 | 06 Nov 2020 08:05:25 |
| Data point term sent to Coder                                                                                                                                                                                                                          | System                           | 22 Oct 2020 00:18:42 |
| Query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 06). ' answered with 'updated' (Site from DM). | Julia Klopfer (b) (4)<br>(b) (4) | 22 Oct 2020 00:18:00 |
| Coding entries removed.                                                                                                                                                                                                                                | Julia Klopfer (b) (4)<br>(b) (4) | 22 Oct 2020 00:17:49 |
| User entered 'ORTHOSTATIC PRE-SYNCOPE' reason for change: Data Entry Error                                                                                                                                                                             | Julia Klopfer (b) (4)<br>(b) (4) | 22 Oct 2020 00:17:49 |
| User opened query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 06). ' (Site from DM).             | (b) (4), (b) (6)                 | 19 Oct 2020 17:23:03 |



US3432229

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:22:31

[Condition](#)

| Audit                                                                                                                                                                                                   | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Presyncope, LLT: Orthostatic presyncope - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Sep 2020 09:14:42 |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.                                                                                                                   | Coder Import (b) (4) | 19 Sep 2020 09:14:42 |
| Data point term sent to Coder                                                                                                                                                                           | System               | 18 Sep 2020 16:10:19 |
| User entered 'Pre-syncopy/orthostatic'                                                                                                                                                                  | Bruce Bausk (b) (4)  | 18 Sep 2020 16:10:12 |
|                                                                                                                                                                                                         | (b) (4)              |                      |

US3432229

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 2009' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:10:12 |

US3432229

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:10:12 |

US3432229

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Condition ongoing at study entry](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:10:12 |

US3432229

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:10:12 |

US3432229

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:10:12 |

US3432229

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2009' | System | 18 Sep 2020 16:10:12 |

US3432229

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2009' | System | 18 Sep 2020 16:10:12 |



US3432229

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Sep 2020 16:10:12 |

US3432229

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Sep 2020 16:10:12 |

US3432229

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:22:31

[Condition](#)

| Audit                                                                                                                                                                                                                                 | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation and uterine bleeding NEC, PT: Dysmenorrhoea, LLT: Dysmenorrhea - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Sep 2020 16:13:59 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                          | Coder Import (b) (4) | 18 Sep 2020 16:13:59 |
| Data point term sent to Coder                                                                                                                                                                                                         | System               | 18 Sep 2020 16:12:23 |
| User entered 'Dysmenorrhea'                                                                                                                                                                                                           | Bruce Bausk (b) (4)  | 18 Sep 2020 16:11:28 |
|                                                                                                                                                                                                                                       | (b) (4)              |                      |

US3432229

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 2008' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:11:28 |

US3432229

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:11:28 |

US3432229

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Condition ongoing at study entry](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:11:28 |

US3432229

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:11:28 |

US3432229

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:11:28 |



US3432229

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2008' | System | 18 Sep 2020 16:11:28 |

US3432229

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2008' | System | 18 Sep 2020 16:11:28 |

US3432229

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Sep 2020 16:11:28 |

US3432229

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Sep 2020 16:11:28 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[Were vital signs assessed?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:36:31 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '21 Aug 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:36:31 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                          | Time (GMT)           |
|----------------------|-------------------------------|----------------------|
| User entered '10:32' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:36:31 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 10:32' | System | 21 Aug 2020 16:36:31 |



US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User entered '159.1' cm   | Xhoi Mitre (b) (4) | 21 Aug 2020 16:36:31 |
| DataPoint set to visible. | (b) (4)<br>System  | 21 Aug 2020 16:01:14 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User entered '067.2' kg   | Xhoi Mitre (b) (4) | 21 Aug 2020 16:36:31 |
| DataPoint set to visible. | (b) (4)<br>System  | 21 Aug 2020 16:01:14 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                      | User   | Time (GMT)           |
|--------------------------------------------|--------|----------------------|
| Amendment Manager: User entered '26.54782' | System | 17 Sep 2020 00:17:58 |
| User entered '26.5'                        | System | 21 Aug 2020 16:36:31 |
| DataPoint set to visible.                  | System | 21 Aug 2020 16:01:14 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[BMI units](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered 'kg/m2'      | System | 21 Aug 2020 16:36:31 |
| DataPoint set to visible. | System | 21 Aug 2020 16:01:14 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:36:31 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[Route of measurement](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:36:31 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[If Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:36:31 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[Pulse \(xxx\)](#)

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:36:31 |



US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 21 Aug 2020 16:36:31 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:36:31 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 21 Aug 2020 16:36:31 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:36:31 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Aug 2020 16:36:31 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:36:31 |

US3432229

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Aug 2020 16:36:31 |

US3432229

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:22:31**

[Was the physical examination performed?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:33:02 |



US3432229

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '21 Aug 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:33:02 |

US3432229

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:22:31**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '21 Aug 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:33:40 |

US3432229

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:33:40 |

US3432229

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:22:31**

[If No, what is the reason?](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:33:40 |

US3432229

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:22:31**

[If Partner medically sterile or Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:33:40 |

US3432229

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:33:40 |

US3432229

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:22:31**

[Date of surgery unknown](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:33:40 |

US3432229

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:33:40 |



US3432229

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:22:31**

[Date of last menstruation unknown](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:33:40 |

US3432229

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

[Was the pregnancy test performed?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:34:12 |

US3432229

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

[Date of test \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '21 Aug 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:34:12 |

US3432229

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

[Test performed](#)

| Audit                        | User                          | Time (GMT)           |
|------------------------------|-------------------------------|----------------------|
| User entered 'Urine (URINE)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:34:12 |

US3432229

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

[Result](#)

| Audit                              | User                          | Time (GMT)           |
|------------------------------------|-------------------------------|----------------------|
| User entered 'Negative (NEGATIVE)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:34:12 |

US3432229

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

[Was FSH sample collected?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:34:12 |

US3432229

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

[Collection date](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:34:12 |

US3432229

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

[Collection time](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:34:12 |



US3432229

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 16:34:12 |

US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

**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)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

**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)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |



US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

**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)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

**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 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

**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)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

**Other**

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

[Specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

**No Risk Identified**

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |



US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

**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' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '1' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder:** Screening

**Form:** Risk of Exposure

**Generated On:** 26 Nov 2020 09:22:31

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

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder:** Screening

**Form:** Risk of Exposure

**Generated On:** 26 Nov 2020 09:22:31

**Resides in a single family home** (i.e., detached housing)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

**Other**

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:22:31**

[Specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:35:20 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:22:31**

[Was this visit performed?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:01:47 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '21 Aug 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:01:47 |



US3432229

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                          | User                          | Time (GMT)           |
|--------------------------------|-------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:01:47 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:22:31**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 21 Aug 2020 16:01:47 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                                            | Time (GMT)           |
|----------------------------|-------------------------------------------------|----------------------|
| User entered '21 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 21 Aug 2020 15:29:49 |

US3432229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

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

| Audit                 | User                                            | Time (GMT)           |
|-----------------------|-------------------------------------------------|----------------------|
| User entered '144547' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 21 Aug 2020 15:29:49 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                             | User                                           | Time (GMT)           |
|---------------------------------------------------|------------------------------------------------|----------------------|
| User entered '>=18 and <65 years and at risk (2)' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 21 Aug 2020 15:29:49 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:22:31**

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 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:31:41 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:31:41 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:31:41 |



US3432229

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:31:41 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:22:31**

[Liver Disease](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:31:41 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                        | User   | Time (GMT)           |
|----------------------------------------------|--------|----------------------|
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 10:38:04 |
| Amendment Manager inserted this DataPoint.   | System | 19 Sep 2020 01:57:52 |

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

Height

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

Weight

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

Height

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

Weight

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Timepoint](#)

| Audit                                            | User                          | Time (GMT)           |
|--------------------------------------------------|-------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |



US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

[Were vital signs assessed?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '21 Aug 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                          | Time (GMT)           |
|----------------------|-------------------------------|----------------------|
| User entered '10:32' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 10:32' | System | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

Temperature (xxx.x)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered '36.5' C | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

[Route of measurement](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'Oral (Oral)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

[If Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Pulse \(xxx\)](#)

| Audit              | User                          | Time (GMT)           |
|--------------------|-------------------------------|----------------------|
| User entered '077' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |



US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit             | User                          | Time (GMT)           |
|-------------------|-------------------------------|----------------------|
| User entered '10' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit              | User                          | Time (GMT)           |
|--------------------|-------------------------------|----------------------|
| User entered '121' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit              | User                          | Time (GMT)           |
|--------------------|-------------------------------|----------------------|
| User entered '069' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 09:22:31**

[Height](#)

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |



US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

Weight

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered missing code ND - Not Done. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Timepoint](#)

| Audit                                              | User                          | Time (GMT)           |
|----------------------------------------------------|-------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

[Were vital signs assessed?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '21 Aug 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                          | Time (GMT)           |
|----------------------|-------------------------------|----------------------|
| User entered '13:26' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 13:26' | System | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

Temperature (xxx.x)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered '37.1' C | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

[Route of measurement](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'Oral (Oral)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |



US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

[If Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Pulse \(xxx\)](#)

| Audit              | User                          | Time (GMT)           |
|--------------------|-------------------------------|----------------------|
| User entered '073' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit             | User                          | Time (GMT)           |
|-------------------|-------------------------------|----------------------|
| User entered '14' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit              | User                          | Time (GMT)           |
|--------------------|-------------------------------|----------------------|
| User entered '124' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Aug 2020 22:09:47 |

US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit              | User                          | Time (GMT)           |
|--------------------|-------------------------------|----------------------|
| User entered '075' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:09:47 |



US3432229

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:22:31**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Aug 2020 22:09:47 |

US3432229

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

[Was the physical examination performed?](#)

| Audit                                                     | User               | Time (GMT)           |
|-----------------------------------------------------------|--------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | Xhoi Mitre (b) (4) | 21 Aug 2020 16:32:46 |
| User entered 'Yes (Y)'                                    | Xhoi Mitre (b) (4) | 21 Aug 2020 16:32:26 |

US3432229

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Date of examination (*dd MMM yyyy*)

| Audit                                                  | User               | Time (GMT)           |
|--------------------------------------------------------|--------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Xhoi Mitre (b) (4) | 21 Aug 2020 16:32:46 |
| User entered '21 Aug 2020'                             | Xhoi Mitre (b) (4) | 21 Aug 2020 16:32:26 |

US3432229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Was the pregnancy test performed?](#)

| Audit                                                                                                                                                                                                                                           | User                    | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User closed query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).                                    | (b) (4), (b) (6)        | 06 Nov 2020 08:02:29 |
| Query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' answered with 'This is against EDC guidelines' (Site from DM). | Alexander Mills (b) (4) | 22 Oct 2020 17:31:34 |
| User entered 'No (N)' reason for change: Data Entry Error                                                                                                                                                                                       | Alexander Mills (b) (4) | 22 Oct 2020 17:30:28 |
| User opened query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).                                    | (b) (4), (b) (6)        | 06 Oct 2020 14:47:37 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                          | Xhoi Mitre (b) (4)      | 21 Aug 2020 16:45:34 |

US3432229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

Date of test (dd MMM yyyy)

| Audit                                                  | User                    | Time (GMT)           |
|--------------------------------------------------------|-------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Alexander Mills (b) (4) | 22 Oct 2020 17:30:28 |
| User entered '21 Aug 2020'                             | Xhoi Mitre (b) (4)      | 21 Aug 2020 16:45:34 |

US3432229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Test performed](#)

| Audit                                                  | User                    | Time (GMT)           |
|--------------------------------------------------------|-------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Alexander Mills (b) (4) | 22 Oct 2020 17:30:28 |
| User entered 'Urine (URINE)'                           | Xhoi Mitre (b) (4)      | 21 Aug 2020 16:45:34 |

US3432229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Result](#)

| Audit                                                  | User                    | Time (GMT)           |
|--------------------------------------------------------|-------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Alexander Mills (b) (4) | 22 Oct 2020 17:30:28 |
| User entered 'Negative (NEGATIVE)'                     | Xhoi Mitre (b) (4)      | 21 Aug 2020 16:45:34 |

US3432229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Was FSH sample collected?](#)

| Audit                                                                                                                              | User                               | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User closed query 'Per CDM: A response Yes/No is required for this field. Please update accordingly. ' (Site from DM).             | (b) (4), (b) (6)                   | 10 Nov 2020 08:04:24 |
| Query 'Per CDM: A response Yes/No is required for this field. Please update accordingly. ' answered with 'updated' (Site from DM). | Julia Klopfer (b) (4)<br>(b) (4)   | 06 Nov 2020 18:37:23 |
| User entered 'No (N)' reason for change: Data Entry Error                                                                          | Julia Klopfer (b) (4)<br>(b) (4)   | 06 Nov 2020 18:37:17 |
| User opened query 'Per CDM: A response Yes/No is required for this field. Please update accordingly. ' (Site from DM).             | (b) (4), (b) (6)                   | 06 Nov 2020 08:02:38 |
| User entered empty; reason for change Data Entry Error                                                                             | Alexander Mills (b) (4)<br>(b) (4) | 22 Oct 2020 17:30:28 |
| User entered 'No (N)'                                                                                                              | Xhoi Mitre (b) (4)<br>(b) (4)      | 21 Aug 2020 16:45:34 |



US3432229

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

[Collection date](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:45:34 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

[Collection time](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 16:45:34 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 16:45:34 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:22:31**

[Was study treatment given?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:22:31**

[If No, reason not given](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:22:31**

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '21 Aug 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 17:08:42 |



US3432229

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                | User                          | Time (GMT)           |
|----------------------|-------------------------------|----------------------|
| User entered '12:56' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 12:56' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

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

| Audit                              | User                          | Time (GMT)           |
|------------------------------------|-------------------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:22:31**

[Was the sample collected?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 21:44:23 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '21 Aug 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 21:44:23 |

US3432229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

Collection time (00:00-23:59)

| Audit                                                    | User                          | Time (GMT)           |
|----------------------------------------------------------|-------------------------------|----------------------|
| User entered '11:00' reason for change: Data Entry Error | (b) (4), (b) (6)              | 28 Sep 2020 18:06:58 |
| User entered '11:27'                                     | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 21:44:23 |



US3432229

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:00' | System | 28 Sep 2020 18:06:58 |
| User entered '21 Aug 2020 11:27' | System | 21 Aug 2020 21:44:23 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '21 Aug 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 21:44:46 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Lab Test](#)

| Audit                                                        | User               | Time (GMT)           |
|--------------------------------------------------------------|--------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Xhoi Mitre (b) (4) | 21 Aug 2020 21:44:46 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Was the sample collected?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 21:44:46 |

US3432229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

Collection time (00:00 - 23:59)

| Audit                                                    | User                          | Time (GMT)           |
|----------------------------------------------------------|-------------------------------|----------------------|
| User entered '11:05' reason for change: Data Entry Error | (b) (4), (b) (6)              | 28 Sep 2020 18:07:06 |
| User entered '11:32'                                     | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 21:44:46 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:05' | System | 28 Sep 2020 18:07:06 |
| User entered '21 Aug 2020 11:32' | System | 21 Aug 2020 21:44:46 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Lab Test](#)

| Audit                                                        | User               | Time (GMT)           |
|--------------------------------------------------------------|--------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Xhoi Mitre (b) (4) | 21 Aug 2020 21:44:46 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Was the sample collected?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 21:44:46 |



US3432229

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Collection time \(00:00 - 23:59\)](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 21:44:46 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 21:44:46 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 21:44:51 |

US3432229

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 21:44:51 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:30:42', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '07fb2627-40bc-47b5-a10a-2971e14694e3' | System | 21 Aug 2020 17:31:05 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 21 Aug 2020 17:31:05 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:30:50', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '07fb2627-40bc-47b5-a10a-2971e14694e3' | System | 21 Aug 2020 17:31:05 |
| User entered '98.8'                                                                                                                                                                                                                                            | System | 21 Aug 2020 17:31:05 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:30:54', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '07fb2627-40bc-47b5-a10a-2971e14694e3' | System | 21 Aug 2020 17:31:05 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Aug 2020 17:31:05 |



US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:31:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '07fb2627-40bc-47b5-a10a-2971e14694e3' | System | 21 Aug 2020 17:31:05 |
| User entered '21 Aug 2020 13:31'                                                                                                                                                                                                                               | System | 21 Aug 2020 17:31:05 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 13:16' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 15:46' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 1, after vaccination (at home)' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:09', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2a9b15d5-20e8-49c7-ad3d-cd0becda0268' | System | 21 Aug 2020 20:50:23 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 21 Aug 2020 20:50:23 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:14', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2a9b15d5-20e8-49c7-ad3d-cd0becda0268' | System | 21 Aug 2020 20:50:23 |
| User entered '98.6'                                                                                                                                                                                                                                            | System | 21 Aug 2020 20:50:23 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:16', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2a9b15d5-20e8-49c7-ad3d-cd0becda0268' | System | 21 Aug 2020 20:50:23 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Aug 2020 20:50:23 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:20', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2a9b15d5-20e8-49c7-ad3d-cd0becda0268' | System | 21 Aug 2020 20:50:23 |
| User entered '21 Aug 2020 16:50'                                                                                                                                                                                                                               | System | 21 Aug 2020 20:50:23 |



US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 16:41' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 2' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:39:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6b71e39f-9071-4466-a728-723d71c23aee' | System | 22 Aug 2020 22:40:09 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 22 Aug 2020 22:40:09 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:39:53', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6b71e39f-9071-4466-a728-723d71c23aee' User entered '98.3' | System | 22 Aug 2020 22:40:09 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:39:57', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6b71e39f-9071-4466-a728-723d71c23aee' | System | 22 Aug 2020 22:40:09 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 22 Aug 2020 22:40:09 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | User                         | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|----------------------|
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and meloxicam noted in the e-diary' (Site from System). | (b) (4), (b) (6)             | 07 Sep 2020 09:01:59 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:03', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6b71e39f-9071-4466-a728-723d71c23aee' User entered '1'                                             | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:17:24 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | System                       | 22 Aug 2020 22:40:09 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | System                       | 22 Aug 2020 22:40:09 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | System                       | 22 Aug 2020 22:40:09 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:22:31

To **PREVENT** pain or fever from occurring

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:03', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6b71e39f-9071-4466-a728-723d71c23aee' | System | 22 Aug 2020 22:40:09 |
| User entered '0'                                                                                                                                                                                                                                               | System | 22 Aug 2020 22:40:09 |



US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:05', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6b71e39f-9071-4466-a728-723d71c23aee' | System | 22 Aug 2020 22:40:09 |
| User entered '22 Aug 2020 18:40'                                                                                                                                                                                                                               | System | 22 Aug 2020 22:40:09 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 3' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '700ade04-cd34-4a3e-85e3-3bf6b95aca5d' | System | 24 Aug 2020 14:48:25 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 24 Aug 2020 14:48:25 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:04', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '700ade04-cd34-4a3e-85e3-3bf6b95aca5d' | System | 24 Aug 2020 14:48:25 |
| User entered '98.3'                                                                                                                                                                                                                                            | System | 24 Aug 2020 14:48:25 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '700ade04-cd34-4a3e-85e3-3bf6b95aca5d' | System | 24 Aug 2020 14:48:25 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 24 Aug 2020 14:48:25 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | User                         | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|----------------------|
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and meloxicam noted in the e-diary' (Site from System). | (b) (4), (b) (6)             | 07 Sep 2020 09:02:20 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:21', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '700ade04-cd34-4a3e-85e3-3bf6b95aca5d' User entered '1'                                             | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:17:14 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | System                       | 24 Aug 2020 14:48:25 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | System                       | 24 Aug 2020 14:48:25 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | System                       | 24 Aug 2020 14:48:25 |



US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:22:31

To **PREVENT** pain or fever from occurring

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | User                         | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|----------------------|
| User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and meloxicam noted in the e-diary' (Site from System). | (b) (4), (b) (6)             | 07 Sep 2020 09:02:26 |
| User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:21', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '700ade04-cd34-4a3e-85e3-3bf6b95aca5d' User entered '1'                                               | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:17:19 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | System                       | 24 Aug 2020 14:48:25 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | System                       | 24 Aug 2020 14:48:25 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | System                       | 24 Aug 2020 14:48:25 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:23', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '700ade04-cd34-4a3e-85e3-3bf6b95aca5d' | System | 24 Aug 2020 14:48:25 |
| User entered '24 Aug 2020 10:48'                                                                                                                                                                                                                               | System | 24 Aug 2020 14:48:25 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 4' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:39:34', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '9444a6f7-0faa-473c-abef-1781c665319c' | System | 25 Aug 2020 02:40:32 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 25 Aug 2020 02:40:32 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

Please record your **TEMPERATURE in °F**

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:40:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '9444a6f7-0faa-473c-abef-1781c665319c' User entered '98.3' | System | 25 Aug 2020 02:40:32 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:40:28', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '9444a6f7-0faa-473c-abef-1781c665319c' | System | 25 Aug 2020 02:40:32 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 25 Aug 2020 02:40:32 |



US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:40:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '9444a6f7-0faa-473c-abef-1781c665319c' | System | 25 Aug 2020 02:40:32 |
| User entered '24 Aug 2020 22:40'                                                                                                                                                                                                                               | System | 25 Aug 2020 02:40:32 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 5' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:05', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3aaeca1-29c2-46f2-8360-1674c148981f' | System | 26 Aug 2020 02:43:29 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 26 Aug 2020 02:43:29 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:18', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3aaeca1-29c2-46f2-8360-1674c148981f' | System | 26 Aug 2020 02:43:29 |
| User entered '98.3'                                                                                                                                                                                                                                            | System | 26 Aug 2020 02:43:29 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:22', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3aaeca1-29c2-46f2-8360-1674c148981f' | System | 26 Aug 2020 02:43:29 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 26 Aug 2020 02:43:29 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3aaeca1-29c2-46f2-8360-1674c148981f' | System | 26 Aug 2020 02:43:29 |
| User entered '25 Aug 2020 22:43'                                                                                                                                                                                                                               | System | 26 Aug 2020 02:43:29 |



US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 6' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ddb38b4-5108-4fac-80ff-f582102c0d77' | System | 27 Aug 2020 11:55:43 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                        | System | 27 Aug 2020 11:55:43 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ddb38b4-5108-4fac-80ff-f582102c0d77' | System | 27 Aug 2020 11:55:43 |
| User entered '98.3'                                                                                                                                                                                                                                           | System | 27 Aug 2020 11:55:43 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:34', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ddb38b4-5108-4fac-80ff-f582102c0d77' | System | 27 Aug 2020 11:55:43 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                        | System | 27 Aug 2020 11:55:43 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | User                         | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|----------------------|
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and meloxicam noted in the e-diary' (Site from System). | (b) (4), (b) (6)             | 07 Sep 2020 09:02:39 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and meloxicam noted in the e-diary' (Site from System).                                                                                                                                                                                                                                                    | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:17:03 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).                                                                                                                                                                                                                                                                                                                             | System                       | 27 Aug 2020 11:55:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:36', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ddb38b4-5108-4fac-80ff-f582102c0d77'                                                                                                                                                                                                                                                                                                                              | System                       | 27 Aug 2020 11:55:43 |
| User entered '1'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | System                       | 27 Aug 2020 11:55:43 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:22:31

To **PREVENT** pain or fever from occurring

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:36', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ddb38b4-5108-4fac-80ff-f582102c0d77' | System | 27 Aug 2020 11:55:43 |
| User entered '0'                                                                                                                                                                                                                                              | System | 27 Aug 2020 11:55:43 |



US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:38', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ddb38b4-5108-4fac-80ff-f582102c0d77' | System | 27 Aug 2020 11:55:43 |
| User entered '27 Aug 2020 07:55'                                                                                                                                                                                                                              | System | 27 Aug 2020 11:55:43 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 7' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ebb93ed9-51ea-46da-b555-e61112d794a7' | System | 28 Aug 2020 03:59:44 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 28 Aug 2020 03:59:44 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:36', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ebb93ed9-51ea-46da-b555-e61112d794a7' | System | 28 Aug 2020 03:59:44 |
| User entered '98.3'                                                                                                                                                                                                                                            | System | 28 Aug 2020 03:59:44 |

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:39', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ebb93ed9-51ea-46da-b555-e61112d794a7' | System | 28 Aug 2020 03:59:44 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 28 Aug 2020 03:59:44 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ebb93ed9-51ea-46da-b555-e61112d794a7' | System | 28 Aug 2020 03:59:44 |
| User entered '27 Aug 2020 23:59'                                                                                                                                                                                                                               | System | 28 Aug 2020 03:59:44 |



US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:31:10', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '71a08012-5163-42e0-92f1-cf464a0763e0' | System | 21 Aug 2020 17:34:34 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 21 Aug 2020 17:34:34 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:31:20', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '71a08012-5163-42e0-92f1-cf464a0763e0' | System | 21 Aug 2020 17:34:34 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 21 Aug 2020 17:34:34 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Please record - REDNESS AT INJECTION SITE (in mm)

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

| Audit                                                                                                                                                                                                                                                                            | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:32:59', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '71a08012-5163-42e0-92f1-cf464a0763e0' User entered '53' | System | 21 Aug 2020 17:34:34 |
|                                                                                                                                                                                                                                                                                  | System | 21 Aug 2020 17:34:34 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:33:09', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '71a08012-5163-42e0-92f1-cf464a0763e0' | System | 21 Aug 2020 17:34:34 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 21 Aug 2020 17:34:34 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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

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

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:33:57', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '71a08012-5163-42e0-92f1-cf464a0763e0' User entered '5' | System | 21 Aug 2020 17:34:34 |
|                                                                                                                                                                                                                                                                                 | System | 21 Aug 2020 17:34:34 |



US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:04', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '71a08012-5163-42e0-92f1-cf464a0763e0' | System | 21 Aug 2020 17:34:34 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 21 Aug 2020 17:34:34 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '71a08012-5163-42e0-92f1-cf464a0763e0' | System | 21 Aug 2020 17:34:34 |
| User entered '21 Aug 2020 13:34'                                                                                                                                                                                                                               | System | 21 Aug 2020 17:34:34 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 13:16' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 15:46' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 1, after vaccination (at home)' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:51:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bf98b21a-3918-4478-80cc-8c90d85caa38' | System | 21 Aug 2020 20:52:27 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 21 Aug 2020 20:52:27 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:52:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bf98b21a-3918-4478-80cc-8c90d85caa38' | System | 21 Aug 2020 20:52:27 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Aug 2020 20:52:27 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:52:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bf98b21a-3918-4478-80cc-8c90d85caa38' | System | 21 Aug 2020 20:52:27 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Aug 2020 20:52:27 |



US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:52:21', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bf98b21a-3918-4478-80cc-8c90d85caa38' | System | 21 Aug 2020 20:52:27 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 21 Aug 2020 20:52:27 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:52:24', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bf98b21a-3918-4478-80cc-8c90d85caa38' | System | 21 Aug 2020 20:52:27 |
| User entered '21 Aug 2020 16:52'                                                                                                                                                                                                                               | System | 21 Aug 2020 20:52:27 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 16:41' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 2' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:15', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3228485-4d09-4347-9cd7-a6f99b85e7e7' | System | 22 Aug 2020 22:40:37 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'                                                                                                                                                       | System | 22 Aug 2020 22:40:37 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:17', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3228485-4d09-4347-9cd7-a6f99b85e7e7' | System | 22 Aug 2020 22:40:37 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Aug 2020 22:40:37 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:25', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3228485-4d09-4347-9cd7-a6f99b85e7e7' | System | 22 Aug 2020 22:40:37 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Aug 2020 22:40:37 |



US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3228485-4d09-4347-9cd7-a6f99b85e7e7' | System | 22 Aug 2020 22:40:37 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 22:40:37 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:32', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3228485-4d09-4347-9cd7-a6f99b85e7e7' | System | 22 Aug 2020 22:40:37 |
| User entered '22 Aug 2020 18:40'                                                                                                                                                                                                                               | System | 22 Aug 2020 22:40:37 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 3' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:31', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '04b44373-dc3d-4555-b43c-bbd54522239b' | System | 24 Aug 2020 14:48:41 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'                                                                                                                                                       | System | 24 Aug 2020 14:48:41 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:32', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '04b44373-dc3d-4555-b43c-bbd54522239b' | System | 24 Aug 2020 14:48:41 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Aug 2020 14:48:41 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:35', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '04b44373-dc3d-4555-b43c-bbd54522239b' | System | 24 Aug 2020 14:48:41 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Aug 2020 14:48:41 |



US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '04b44373-dc3d-4555-b43c-bbd54522239b' | System | 24 Aug 2020 14:48:41 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 14:48:41 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:39', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '04b44373-dc3d-4555-b43c-bbd54522239b' | System | 24 Aug 2020 14:48:41 |
| User entered '24 Aug 2020 10:48'                                                                                                                                                                                                                               | System | 24 Aug 2020 14:48:41 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 4' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ff3e7bb-9821-40f2-a3ad-416e71c2c729' | System | 25 Aug 2020 02:38:18 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 25 Aug 2020 02:38:18 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:10', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ff3e7bb-9821-40f2-a3ad-416e71c2c729' | System | 25 Aug 2020 02:38:18 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 25 Aug 2020 02:38:18 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ff3e7bb-9821-40f2-a3ad-416e71c2c729' | System | 25 Aug 2020 02:38:18 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 25 Aug 2020 02:38:18 |



US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:13', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ff3e7bb-9821-40f2-a3ad-416e71c2c729' | System | 25 Aug 2020 02:38:18 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 25 Aug 2020 02:38:18 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:15', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ff3e7bb-9821-40f2-a3ad-416e71c2c729' | System | 25 Aug 2020 02:38:18 |
| User entered '24 Aug 2020 22:38'                                                                                                                                                                                                                               | System | 25 Aug 2020 02:38:18 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 5' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:31', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7253ed26-1108-4411-a22d-a5733987548b' | System | 26 Aug 2020 02:43:42 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 02:43:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:33', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7253ed26-1108-4411-a22d-a5733987548b' | System | 26 Aug 2020 02:43:42 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 26 Aug 2020 02:43:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:35', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7253ed26-1108-4411-a22d-a5733987548b' | System | 26 Aug 2020 02:43:42 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 26 Aug 2020 02:43:42 |



US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7253ed26-1108-4411-a22d-a5733987548b' | System | 26 Aug 2020 02:43:42 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 02:43:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:39', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7253ed26-1108-4411-a22d-a5733987548b' | System | 26 Aug 2020 02:43:42 |
| User entered '25 Aug 2020 22:43'                                                                                                                                                                                                                               | System | 26 Aug 2020 02:43:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 6' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '826cbc0c-ec93-4e5c-9acc-a54e474c2398' | System | 27 Aug 2020 11:55:53 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 27 Aug 2020 11:55:53 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:42', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '826cbc0c-ec93-4e5c-9acc-a54e474c2398' | System | 27 Aug 2020 11:55:53 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 27 Aug 2020 11:55:53 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '826cbc0c-ec93-4e5c-9acc-a54e474c2398' | System | 27 Aug 2020 11:55:53 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 27 Aug 2020 11:55:53 |



US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:49', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '826cbc0c-ec93-4e5c-9acc-a54e474c2398' | System | 27 Aug 2020 11:55:53 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 27 Aug 2020 11:55:53 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:51', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '826cbc0c-ec93-4e5c-9acc-a54e474c2398' | System | 27 Aug 2020 11:55:53 |
| User entered '27 Aug 2020 07:55'                                                                                                                                                                                                                               | System | 27 Aug 2020 11:55:53 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 7' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:44', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a56bb5b6-12d7-41ee-8c5e-2eed2f1a63cb' | System | 28 Aug 2020 03:59:55 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 28 Aug 2020 03:59:55 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:46', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a56bb5b6-12d7-41ee-8c5e-2eed2f1a63cb' | System | 28 Aug 2020 03:59:55 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 28 Aug 2020 03:59:55 |

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:49', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a56bb5b6-12d7-41ee-8c5e-2eed2f1a63cb' | System | 28 Aug 2020 03:59:55 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 28 Aug 2020 03:59:55 |



US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:52', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a56bb5b6-12d7-41ee-8c5e-2eed2f1a63cb' | System | 28 Aug 2020 03:59:55 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 28 Aug 2020 03:59:55 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:54', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a56bb5b6-12d7-41ee-8c5e-2eed2f1a63cb' | System | 28 Aug 2020 03:59:55 |
| User entered '27 Aug 2020 23:59'                                                                                                                                                                                                                               | System | 28 Aug 2020 03:59:55 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:16', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ad492cd9-ac87-4bce-9a64-c3282a4c21d3' | System | 21 Aug 2020 17:34:54 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 21 Aug 2020 17:34:54 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:21', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ad492cd9-ac87-4bce-9a64-c3282a4c21d3' | System | 21 Aug 2020 17:34:54 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Aug 2020 17:34:54 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:24', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ad492cd9-ac87-4bce-9a64-c3282a4c21d3' | System | 21 Aug 2020 17:34:54 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 21 Aug 2020 17:34:54 |



US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:28', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ad492cd9-ac87-4bce-9a64-c3282a4c21d3' | System | 21 Aug 2020 17:34:54 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Aug 2020 17:34:54 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:33', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ad492cd9-ac87-4bce-9a64-c3282a4c21d3' | System | 21 Aug 2020 17:34:54 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Aug 2020 17:34:54 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ad492cd9-ac87-4bce-9a64-c3282a4c21d3' | System | 21 Aug 2020 17:34:54 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Aug 2020 17:34:54 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ad492cd9-ac87-4bce-9a64-c3282a4c21d3' | System | 21 Aug 2020 17:34:54 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Aug 2020 17:34:54 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:50', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ad492cd9-ac87-4bce-9a64-c3282a4c21d3' | System | 21 Aug 2020 17:34:54 |
| User entered '21 Aug 2020 13:34'                                                                                                                                                                                                                               | System | 21 Aug 2020 17:34:54 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 13:16' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 15:46' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 1, after vaccination (at home)' | System | 21 Aug 2020 17:08:42 |



US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:29', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bffc2fa9-1c65-4224-94df-3eebde7983a2' | System | 21 Aug 2020 20:51:04 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 21 Aug 2020 20:51:04 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:33', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bffc2fa9-1c65-4224-94df-3eebde7983a2' | System | 21 Aug 2020 20:51:04 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 21 Aug 2020 20:51:04 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:43', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bffc2fa9-1c65-4224-94df-3eebde7983a2' | System | 21 Aug 2020 20:51:04 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 21 Aug 2020 20:51:04 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bffc2fa9-1c65-4224-94df-3eebde7983a2' | System | 21 Aug 2020 20:51:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Aug 2020 20:51:04 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:49', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bffc2fa9-1c65-4224-94df-3eebde7983a2' | System | 21 Aug 2020 20:51:04 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'                                                                                                                                                                                      | System | 21 Aug 2020 20:51:04 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:54', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bffc2fa9-1c65-4224-94df-3eebde7983a2' | System | 21 Aug 2020 20:51:04 |
| User entered 'Some interference with activity not requiring medical attention (2)'                                                                                                                                                                             | System | 21 Aug 2020 20:51:04 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:59', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bffc2fa9-1c65-4224-94df-3eebde7983a2' | System | 21 Aug 2020 20:51:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Aug 2020 20:51:04 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:51:02', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bffc2fa9-1c65-4224-94df-3eebde7983a2' | System | 21 Aug 2020 20:51:04 |
| User entered '21 Aug 2020 16:51'                                                                                                                                                                                                                               | System | 21 Aug 2020 20:51:04 |



US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 16:41' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 2' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6d37dd8f-2825-4e9b-bda9-3766c5c328d0' | System | 22 Aug 2020 22:41:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 22:41:08 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6d37dd8f-2825-4e9b-bda9-3766c5c328d0' | System | 22 Aug 2020 22:41:08 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 22 Aug 2020 22:41:08 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:46', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6d37dd8f-2825-4e9b-bda9-3766c5c328d0' | System | 22 Aug 2020 22:41:08 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 22 Aug 2020 22:41:08 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6d37dd8f-2825-4e9b-bda9-3766c5c328d0' | System | 22 Aug 2020 22:41:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 22:41:08 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:57', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6d37dd8f-2825-4e9b-bda9-3766c5c328d0' | System | 22 Aug 2020 22:41:08 |
| User entered 'Some interference with activity or >2 episodes/24 hours (2)'                                                                                                                                                                                     | System | 22 Aug 2020 22:41:08 |



US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:59', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6d37dd8f-2825-4e9b-bda9-3766c5c328d0' | System | 22 Aug 2020 22:41:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 22:41:08 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:41:03', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6d37dd8f-2825-4e9b-bda9-3766c5c328d0' | System | 22 Aug 2020 22:41:08 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Aug 2020 22:41:08 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:41:06', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6d37dd8f-2825-4e9b-bda9-3766c5c328d0' | System | 22 Aug 2020 22:41:08 |
| User entered '22 Aug 2020 18:41'                                                                                                                                                                                                                               | System | 22 Aug 2020 22:41:08 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 3' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd8a4ab04-b861-46fb-a081-bf1869ecd90d' | System | 24 Aug 2020 14:49:08 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 24 Aug 2020 14:49:08 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:49', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd8a4ab04-b861-46fb-a081-bf1869ecd90d' | System | 24 Aug 2020 14:49:08 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 24 Aug 2020 14:49:08 |



US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:53', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd8a4ab04-b861-46fb-a081-bf1869ecd90d' | System | 24 Aug 2020 14:49:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 14:49:08 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:54', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd8a4ab04-b861-46fb-a081-bf1869ecd90d' | System | 24 Aug 2020 14:49:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 14:49:08 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:57', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd8a4ab04-b861-46fb-a081-bf1869ecd90d' | System | 24 Aug 2020 14:49:08 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'                                                                                                                                                                                      | System | 24 Aug 2020 14:49:08 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:59', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd8a4ab04-b861-46fb-a081-bf1869ecd90d' | System | 24 Aug 2020 14:49:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 14:49:08 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:49:01', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd8a4ab04-b861-46fb-a081-bf1869ecd90d' | System | 24 Aug 2020 14:49:08 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Aug 2020 14:49:08 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:49:03', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd8a4ab04-b861-46fb-a081-bf1869ecd90d' | System | 24 Aug 2020 14:49:08 |
| User entered '24 Aug 2020 10:49'                                                                                                                                                                                                                               | System | 24 Aug 2020 14:49:08 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |



US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 4' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:18', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c941931e-dada-4db2-aef3-a03ceb2a6548' | System | 25 Aug 2020 02:38:45 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 25 Aug 2020 02:38:45 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c941931e-dada-4db2-aef3-a03ceb2a6548' | System | 25 Aug 2020 02:38:45 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 25 Aug 2020 02:38:45 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:23', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c941931e-dada-4db2-aef3-a03ceb2a6548' | System | 25 Aug 2020 02:38:45 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 25 Aug 2020 02:38:45 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:25', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c941931e-dada-4db2-aef3-a03ceb2a6548' | System | 25 Aug 2020 02:38:45 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 25 Aug 2020 02:38:45 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:32', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c941931e-dada-4db2-aef3-a03ceb2a6548' | System | 25 Aug 2020 02:38:45 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'                                                                                                                                                                                      | System | 25 Aug 2020 02:38:45 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

CHILLS

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:34', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c941931e-dada-4db2-aef3-a03ceb2a6548' | System | 25 Aug 2020 02:38:45 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 25 Aug 2020 02:38:45 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:35', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c941931e-dada-4db2-aef3-a03ceb2a6548' | System | 25 Aug 2020 02:38:45 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 25 Aug 2020 02:38:45 |



US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:42', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c941931e-dada-4db2-aef3-a03ceb2a6548' | System | 25 Aug 2020 02:38:45 |
| User entered '24 Aug 2020 22:38'                                                                                                                                                                                                                               | System | 25 Aug 2020 02:38:45 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 5' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:43', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '85142b5e-c51f-48aa-b5cb-5f0726ad0d7e' | System | 26 Aug 2020 02:44:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 02:44:04 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '85142b5e-c51f-48aa-b5cb-5f0726ad0d7e' | System | 26 Aug 2020 02:44:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 02:44:04 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:47', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '85142b5e-c51f-48aa-b5cb-5f0726ad0d7e' | System | 26 Aug 2020 02:44:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 02:44:04 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '85142b5e-c51f-48aa-b5cb-5f0726ad0d7e' User entered 'None (0)' | System | 26 Aug 2020 02:44:04 |
|                                                                                                                                                                                                                                                                                        | System | 26 Aug 2020 02:44:04 |



US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:51', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '85142b5e-c51f-48aa-b5cb-5f0726ad0d7e' | System | 26 Aug 2020 02:44:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 02:44:04 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:54', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '85142b5e-c51f-48aa-b5cb-5f0726ad0d7e' | System | 26 Aug 2020 02:44:04 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 02:44:04 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:59', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '85142b5e-c51f-48aa-b5cb-5f0726ad0d7e' | System | 26 Aug 2020 02:44:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 26 Aug 2020 02:44:04 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:44:01', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '85142b5e-c51f-48aa-b5cb-5f0726ad0d7e' User entered '25 Aug 2020 22:44' | System | 26 Aug 2020 02:44:04 |
|                                                                                                                                                                                                                                                                                                 | System | 26 Aug 2020 02:44:04 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 6' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:56:01', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6e271199-a493-4234-ae18-adbd9f349279' | System | 27 Aug 2020 11:56:20 |
| User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'                                                                                                                                                                     |        | 27 Aug 2020 11:56:20 |



US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:56:04', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6e271199-a493-4234-ae18-adbd9f349279' | System | 27 Aug 2020 11:56:20 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 27 Aug 2020 11:56:20 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:56:05', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6e271199-a493-4234-ae18-adbd9f349279' | System | 27 Aug 2020 11:56:20 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 27 Aug 2020 11:56:20 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:56:06', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6e271199-a493-4234-ae18-adbd9f349279' User entered 'None (0)' | System | 27 Aug 2020 11:56:20 |
|                                                                                                                                                                                                                                                                                        | System | 27 Aug 2020 11:56:20 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:56:12', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6e271199-a493-4234-ae18-adbd9f349279' | System | 27 Aug 2020 11:56:20 |
| User entered 'Some interference with activity or >2 episodes/24 hours (2)'                                                                                                                                                                                     | System | 27 Aug 2020 11:56:20 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:56:13', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6e271199-a493-4234-ae18-adbd9f349279' | System | 27 Aug 2020 11:56:20 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 27 Aug 2020 11:56:20 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:56:16', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6e271199-a493-4234-ae18-adbd9f349279' | System | 27 Aug 2020 11:56:20 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 27 Aug 2020 11:56:20 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:56:17', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6e271199-a493-4234-ae18-adbd9f349279' | System | 27 Aug 2020 11:56:20 |
| User entered '27 Aug 2020 07:56'                                                                                                                                                                                                                               | System | 27 Aug 2020 11:56:20 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |



US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 7' | System | 21 Aug 2020 17:08:42 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:58', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a99d6e2c-e36e-4bd4-adff-0020bc4d2ac1' | System | 28 Aug 2020 04:00:26 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 28 Aug 2020 04:00:26 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-28T00:00:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a99d6e2c-e36e-4bd4-adff-0020bc4d2ac1' | System | 28 Aug 2020 04:00:26 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 28 Aug 2020 04:00:26 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-28T00:00:01', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a99d6e2c-e36e-4bd4-adff-0020bc4d2ac1' | System | 28 Aug 2020 04:00:26 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 28 Aug 2020 04:00:26 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-28T00:00:06', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a99d6e2c-e36e-4bd4-adff-0020bc4d2ac1' | System | 28 Aug 2020 04:00:26 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 28 Aug 2020 04:00:26 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-28T00:00:07', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a99d6e2c-e36e-4bd4-adff-0020bc4d2ac1' | System | 28 Aug 2020 04:00:26 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 28 Aug 2020 04:00:26 |

US3432229

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-28T00:00:09', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a99d6e2c-e36e-4bd4-adff-0020bc4d2ac1' | System | 28 Aug 2020 04:00:26 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 28 Aug 2020 04:00:26 |



US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-28T00:00:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a99d6e2c-e36e-4bd4-adff-0020bc4d2ac1' | System | 28 Aug 2020 04:00:26 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 28 Aug 2020 04:00:26 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-28T00:00:14', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a99d6e2c-e36e-4bd4-adff-0020bc4d2ac1' | System | 28 Aug 2020 04:00:26 |
| User entered '28 Aug 2020 00:00'                                                                                                                                                                                                                               | System | 28 Aug 2020 04:00:26 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 12:00' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 11:59' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Was Contact Attempted?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Julia Klopfer (b) (4)<br>(b) (4) | 29 Aug 2020 17:22:51 |

US3432229

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '29 Aug 2020' | Julia Klopfer (b) (4)<br>(b) (4) | 29 Aug 2020 17:22:51 |

US3432229

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--------------------------------------------|----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Julia Klopfer (b) (4)<br>(b) (4) | 29 Aug 2020 17:22:51 |

US3432229

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Julia Klopfer (b) (4)<br>(b) (4) | 29 Aug 2020 17:22:51 |



US3432229

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Julia Klopfer (b) (4)<br>(b) (4) | 29 Aug 2020 17:22:56 |

US3432229

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Aug 2020 17:22:56 |

US3432229

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Was Contact Attempted?](#)

| Audit                  | User                         | Time (GMT)           |
|------------------------|------------------------------|----------------------|
| User entered 'Yes (Y)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:01:44 |

US3432229

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                                                              | User                      | Time (GMT)           |
|--------------------------------------------------------------------|---------------------------|----------------------|
| User entered '05 Sep 2020' reason for change: Per Query Resolution | Xhoi Mitre (b) (4)        | 10 Nov 2020 15:10:19 |
| User entered '5 Sep 2020'                                          | Phoebe Cunningham (b) (4) | 05 Sep 2020 14:01:44 |

US3432229

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                         | Time (GMT)           |
|--------------------------------------------|------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:01:44 |

US3432229

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                         | Time (GMT)           |
|---------------------|------------------------------|----------------------|
| User entered empty. | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:01:44 |

US3432229

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                  | User                         | Time (GMT)           |
|------------------------|------------------------------|----------------------|
| User entered 'Yes (Y)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:03:36 |

US3432229

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Sep 2020 14:03:36 |



US3432229

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Sep 2020 15:01:15 |
|                        |                  |                      |

US3432229

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '11 Sep 2020' | (b) (4), (b) (6) | 11 Sep 2020 15:01:15 |
|                            |                  |                      |

US3432229

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 11 Sep 2020 15:01:15 |

US3432229

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 11 Sep 2020 15:01:15 |
|                     |                  |                      |

US3432229

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Sep 2020 15:02:43 |
|                        |                  |                      |

US3432229

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Sep 2020 15:02:43 |

US3432229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Was this visit performed?](#)

| Audit                                                                                                                                                                                                              | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per GCL Lab Recon: it appears GCL has a Swab Sample with date 18SEP2020 for Visit 2 Day29 ; however there is no record in EDC. Please reconcile or clarify' (Site from DM).                     | (b) (4), (b) (6)      | 17 Nov 2020 12:47:14 |
| Query 'Per GCL Lab Recon: it appears GCL has a Swab Sample with date 18SEP2020 for Visit 2 Day29 ; however there is no record in EDC. Please reconcile or clarify' answered with 'yes it was done' (Site from DM). | Monica Feeley (b) (4) | 10 Nov 2020 21:55:59 |
| User opened query 'Per GCL Lab Recon: it appears GCL has a Swab Sample with date 18SEP2020 for Visit 2 Day29 ; however there is no record in EDC. Please reconcile or clarify' (Site from DM).                     | (b) (4), (b) (6)      | 22 Oct 2020 11:49:52 |
| User entered 'Yes (Y)'                                                                                                                                                                                             | Bruce Bausk (b) (4)   | 18 Sep 2020 16:15:27 |

US3432229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

Visit date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                                                                                  | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| Query 'Per GCL Lab Reconciliation:<br>Antibody-mediated Immunogenicity: Sample dated 18SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'yes it was done' (Site from DM). | Monica Feeley (b) (4)<br>(b) (4) | 10 Nov 2020 21:56:03 |
| User opened query 'Per GCL Lab Reconciliation:<br>Antibody-mediated Immunogenicity: Sample dated 18SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).                     | (b) (4), (b) (6)<br>(b) (4)      | 23 Oct 2020 05:51:41 |
| User entered '18 Sep 2020'                                                                                                                                                                                                                                                                                                                                             | Bruce Bausk (b) (4)<br>(b) (4)   | 18 Sep 2020 16:15:27 |



US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:15:27 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:22:31**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 18 Sep 2020 16:15:27 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[Timepoint](#)

| Audit                                            | User                           | Time (GMT)           |
|--------------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[Were vital signs assessed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder:** Visit 2 Day 29 (1)

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

**Generated On:** 26 Nov 2020 09:22:31

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '18 Sep 2020' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| User entered '10:47' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 10:47' | System | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

Temperature (xxx.x)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered '37.0' C | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |



US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[Route of measurement](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (Oral)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[If Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[Pulse \(xxx\)](#)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '74' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '14' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit              | User                           | Time (GMT)           |
|--------------------|--------------------------------|----------------------|
| User entered '113' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 18 Sep 2020 16:19:05 |



US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '68' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[Timepoint](#)

| Audit                                              | User                           | Time (GMT)           |
|----------------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder:** Visit 2 Day 29 (1)

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

**Generated On:** 26 Nov 2020 09:22:31

[Were vital signs assessed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '18 Sep 2020' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder:** Visit 2 Day 29 (1)

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

**Generated On:** 26 Nov 2020 09:22:31

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| User entered '11:44' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:44' | System | 18 Sep 2020 16:19:05 |

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Temperature (xxx.x)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered '36.5' C | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |



US3432229

**Folder:** Visit 2 Day 29 (1)

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

**Generated On:** 26 Nov 2020 09:22:31

[Route of measurement](#)

| Audit                        | User                           | Time (GMT)           |
|------------------------------|--------------------------------|----------------------|
| User entered 'Other (Other)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[If Other, specify](#)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered 'IR' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[Pulse \(xxx\)](#)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '73' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '14' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit              | User                           | Time (GMT)           |
|--------------------|--------------------------------|----------------------|
| User entered '109' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 18 Sep 2020 16:19:05 |



US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '61' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:22:31**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 18 Sep 2020 16:19:05 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:22:31**

[Was the physical examination performed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:20:57 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '18 Sep 2020' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:20:57 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

[Was the pregnancy test performed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:21:08 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '18 Sep 2020' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:21:08 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

[Test performed](#)

| Audit                        | User                           | Time (GMT)           |
|------------------------------|--------------------------------|----------------------|
| User entered 'Urine (URINE)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:21:08 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

[Result](#)

| Audit                              | User                           | Time (GMT)           |
|------------------------------------|--------------------------------|----------------------|
| User entered 'Negative (NEGATIVE)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:21:08 |



US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

[Was FSH sample collected?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:21:08 |

US3432229

**Folder:** Visit 2 Day 29 (1)

**Form:** Pregnancy Test

**Generated On:** 26 Nov 2020 09:22:31

[Collection date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:21:08 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

[Collection time](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:21:08 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Sep 2020 16:21:08 |

US3432229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[Was study treatment given?](#)

| Audit                                                                                               | User                           | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| Query 'Per CDM: Please complete Immunogenicity and Central Lab forms. ' canceled (Site from DM).    | (b) (4), (b) (6)               | 02 Nov 2020 06:14:19 |
| User opened query 'Per CDM: Please complete Immunogenicity and Central Lab forms. ' (Site from DM). | (b) (4), (b) (6)               | 06 Oct 2020 21:56:12 |
| User entered 'Yes (Y)'                                                                              | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 15:40:31 |

US3432229

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:22:31

[If No, reason not given](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 15:40:31 |

US3432229

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:22:31

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 18 Sep 2020 15:40:31 |



US3432229

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:22:31

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '18 Sep 2020' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 15:40:31 |

US3432229

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:22:31

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

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| User entered '11:14' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:14' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

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

| Audit                              | User                           | Time (GMT)           |
|------------------------------------|--------------------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 15:40:31 |

US3432229

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:22:31

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:22:31**

[Was the sample collected?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Monica Feeley (b) (4)<br>(b) (4) | 10 Nov 2020 21:56:28 |

US3432229

**Folder:** Visit 2 Day 29 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 09:22:31

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '18 Sep 2020' | Monica Feeley (b) (4)<br>(b) (4) | 10 Nov 2020 21:56:28 |



US3432229

**Folder:** Visit 2 Day 29 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 09:22:31

[Collection time \(00:00-23:59\)](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '11:00' | Monica Feeley (b) (4)<br>(b) (4) | 10 Nov 2020 21:56:28 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:00' | System | 10 Nov 2020 21:56:28 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '18 Sep 2020' | Monica Feeley (b) (4)<br>(b) (4) | 10 Nov 2020 21:56:42 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Lab Test](#)

| Audit                                                        | User                             | Time (GMT)           |
|--------------------------------------------------------------|----------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Monica Feeley (b) (4)<br>(b) (4) | 10 Nov 2020 21:56:42 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Was the sample collected?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Monica Feeley (b) (4)<br>(b) (4) | 10 Nov 2020 21:56:42 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Collection time \(00:00 - 23:59\)](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '11:05' | Monica Feeley (b) (4)<br>(b) (4) | 10 Nov 2020 21:56:42 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:05' | System | 10 Nov 2020 21:56:42 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Lab Test](#)

| Audit                                                        | User                             | Time (GMT)           |
|--------------------------------------------------------------|----------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Monica Feeley (b) (4)<br>(b) (4) | 10 Nov 2020 21:56:42 |



US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Was the sample collected?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Monica Feeley (b) (4)<br>(b) (4) | 10 Nov 2020 21:56:42 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Collection time \(00:00 - 23:59\)](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Monica Feeley (b) (4)<br>(b) (4) | 10 Nov 2020 21:56:42 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Nov 2020 21:56:42 |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Sep 2020 14:40:30 |
|                        |                  |                      |

US3432229

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Sep 2020 14:40:30 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:45:35', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5ebf483a-0036-4051-960e-aa3864f19148' | System | 18 Sep 2020 15:45:49 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 18 Sep 2020 15:45:49 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:45:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5ebf483a-0036-4051-960e-aa3864f19148' User entered '97.7' | System | 18 Sep 2020 15:45:49 |
|                                                                                                                                                                                                                                                                                    | System | 18 Sep 2020 15:45:49 |



US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:45:44', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5ebf483a-0036-4051-960e-aa3864f19148' | System | 18 Sep 2020 15:45:49 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 18 Sep 2020 15:45:49 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:45:46', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5ebf483a-0036-4051-960e-aa3864f19148' | System | 18 Sep 2020 15:45:49 |
| User entered '18 Sep 2020 11:45'                                                                                                                                                                                                                               | System | 18 Sep 2020 15:45:49 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:34' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 14:04' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 1, after vaccination (at home)' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:25', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '19fc3b27-8f0f-4482-88b5-3b12a134e582' | System | 19 Sep 2020 00:50:38 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 19 Sep 2020 00:50:38 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '19fc3b27-8f0f-4482-88b5-3b12a134e582' | System | 19 Sep 2020 00:50:38 |
| User entered '98.3'                                                                                                                                                                                                                                            | System | 19 Sep 2020 00:50:38 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:32', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '19fc3b27-8f0f-4482-88b5-3b12a134e582' | System | 19 Sep 2020 00:50:38 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Sep 2020 00:50:38 |



US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:35', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '19fc3b27-8f0f-4482-88b5-3b12a134e582' | System | 19 Sep 2020 00:50:38 |
| User entered '18 Sep 2020 20:50'                                                                                                                                                                                                                               | System | 19 Sep 2020 00:50:38 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 14:59' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 2' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:16', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5f65ad10-96a5-41bd-abbf-0966b3a12612' | System | 19 Sep 2020 16:54:29 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 19 Sep 2020 16:54:29 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:20', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5f65ad10-96a5-41bd-abbf-0966b3a12612' | System | 19 Sep 2020 16:54:29 |
| User entered '99.3'                                                                                                                                                                                                                                            | System | 19 Sep 2020 16:54:29 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:23', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5f65ad10-96a5-41bd-abbf-0966b3a12612' | System | 19 Sep 2020 16:54:29 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 19 Sep 2020 16:54:29 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | User                         | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|----------------------|
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and ibuprofen and tylenol added to conmedications' (Site from System). | (b) (4), (b) (6)             | 30 Sep 2020 16:46:11 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5f65ad10-96a5-41bd-abbf-0966b3a12612'                                                                             | Phoebe Cunningham<br>(b) (4) | 25 Sep 2020 21:17:38 |
| User entered '1'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | System                       | 19 Sep 2020 16:54:29 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | System                       | 19 Sep 2020 16:54:29 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | System                       | 19 Sep 2020 16:54:29 |



US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:22:31

To **PREVENT** pain or fever from occurring

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5f65ad10-96a5-41bd-abbf-0966b3a12612' | System | 19 Sep 2020 16:54:29 |
| User entered '0'                                                                                                                                                                                                                                               | System | 19 Sep 2020 16:54:29 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:28', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5f65ad10-96a5-41bd-abbf-0966b3a12612' | System | 19 Sep 2020 16:54:29 |
| User entered '19 Sep 2020 12:54'                                                                                                                                                                                                                               | System | 19 Sep 2020 16:54:29 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 3' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:07:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3134c093-052c-42a5-8670-89208c5d4102' | System | 20 Sep 2020 21:07:46 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 20 Sep 2020 21:07:46 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:07:35', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3134c093-052c-42a5-8670-89208c5d4102' | System | 20 Sep 2020 21:07:46 |
| User entered '97.0'                                                                                                                                                                                                                                            | System | 20 Sep 2020 21:07:46 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:07:38', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3134c093-052c-42a5-8670-89208c5d4102' | System | 20 Sep 2020 21:07:46 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 20 Sep 2020 21:07:46 |



US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | User                         | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|----------------------|
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and ibuprofen and tylenol added to conmedications' (Site from System). | (b) (4), (b) (6)             | 30 Sep 2020 16:46:15 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and ibuprofen and tylenol added to conmedications' (Site from System).                                                                                                                                                                                                                                                    | Phoebe Cunningham<br>(b) (4) | 25 Sep 2020 21:17:45 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).                                                                                                                                                                                                                                                                                                                                            | System                       | 20 Sep 2020 21:07:46 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:07:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3134c093-052c-42a5-8670-89208c5d4102'                                                                                                                                                                                                                                                                                                                                            | System                       | 20 Sep 2020 21:07:46 |
| User entered '1'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | System                       | 20 Sep 2020 21:07:46 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:22:31

To **PREVENT** pain or fever from occurring

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | User                         | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|----------------------|
| User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and ibuprofen and tylenol added to conmedications' (Site from System). | (b) (4), (b) (6)             | 30 Sep 2020 16:46:17 |
| User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:07:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3134c093-052c-42a5-8670-89208c5d4102'                                                                               | Phoebe Cunningham<br>(b) (4) | 25 Sep 2020 21:17:49 |
| User entered '1'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | System                       | 20 Sep 2020 21:07:46 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | System                       | 20 Sep 2020 21:07:46 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | System                       | 20 Sep 2020 21:07:46 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:07:43', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3134c093-052c-42a5-8670-89208c5d4102' | System | 20 Sep 2020 21:07:46 |
| User entered '20 Sep 2020 17:07'                                                                                                                                                                                                                               | System | 20 Sep 2020 21:07:46 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 4' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:15', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7997dcfa-7756-495f-b994-f44e9e56f7f8' | System | 22 Sep 2020 04:00:28 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 22 Sep 2020 04:00:28 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:21', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7997dcfa-7756-495f-b994-f44e9e56f7f8' | System | 22 Sep 2020 04:00:28 |
| User entered '97.0'                                                                                                                                                                                                                                            | System | 22 Sep 2020 04:00:28 |



US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:24', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7997dcfa-7756-495f-b994-f44e9e56f7f8' | System | 22 Sep 2020 04:00:28 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Sep 2020 04:00:28 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7997dcfa-7756-495f-b994-f44e9e56f7f8' | System | 22 Sep 2020 04:00:28 |
| User entered '22 Sep 2020 00:00'                                                                                                                                                                                                                               | System | 22 Sep 2020 04:00:28 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 5' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:09', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'da75f623-e940-4e2f-ad95-d26d1e02f4c0' | System | 23 Sep 2020 06:55:29 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 23 Sep 2020 06:55:29 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:20', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'da75f623-e940-4e2f-ad95-d26d1e02f4c0' | System | 23 Sep 2020 06:55:29 |
| User entered '97.0'                                                                                                                                                                                                                                            | System | 23 Sep 2020 06:55:29 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:23', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'da75f623-e940-4e2f-ad95-d26d1e02f4c0' | System | 23 Sep 2020 06:55:29 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Sep 2020 06:55:29 |



US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'da75f623-e940-4e2f-ad95-d26d1e02f4c0' | System | 23 Sep 2020 06:55:29 |
| User entered '23 Sep 2020 02:55'                                                                                                                                                                                                                               | System | 23 Sep 2020 06:55:29 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 6' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:20', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a34f9f5c-5e50-4ece-a062-f0480244d6a3' | System | 24 Sep 2020 01:41:37 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 24 Sep 2020 01:41:37 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:24', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a34f9f5c-5e50-4ece-a062-f0480244d6a3' | System | 24 Sep 2020 01:41:37 |
| User entered '98.2'                                                                                                                                                                                                                                            | System | 24 Sep 2020 01:41:37 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:27', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a34f9f5c-5e50-4ece-a062-f0480244d6a3' | System | 24 Sep 2020 01:41:37 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 24 Sep 2020 01:41:37 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | User                         | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|----------------------|
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and ibuprofen and tylenol added to conmedications' (Site from System). | (b) (4), (b) (6)             | 30 Sep 2020 16:46:26 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a34f9f5c-5e50-4ece-a062-f0480244d6a3'                                                                             | Phoebe Cunningham<br>(b) (4) | 25 Sep 2020 21:18:06 |
| User entered '1'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | System                       | 24 Sep 2020 01:41:37 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | System                       | 24 Sep 2020 01:41:37 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | System                       | 24 Sep 2020 01:41:37 |



US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:22:31

To **PREVENT** pain or fever from occurring

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a34f9f5c-5e50-4ece-a062-f0480244d6a3' | System | 24 Sep 2020 01:41:37 |
| User entered '0'                                                                                                                                                                                                                                               | System | 24 Sep 2020 01:41:37 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:33', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a34f9f5c-5e50-4ece-a062-f0480244d6a3' | System | 24 Sep 2020 01:41:37 |
| User entered '23 Sep 2020 21:41'                                                                                                                                                                                                                               | System | 24 Sep 2020 01:41:37 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 7' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:16', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6eb92e0a-ebb8-441c-b606-6d2f94069bda' User entered 'Yes (Y)' | System | 25 Sep 2020 03:59:32 |
|                                                                                                                                                                                                                                                                                       | System | 25 Sep 2020 03:59:32 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:20', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6eb92e0a-ebb8-441c-b606-6d2f94069bda' User entered '98.3' | System | 25 Sep 2020 03:59:32 |

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:24', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6eb92e0a-ebb8-441c-b606-6d2f94069bda' User entered 'No (N)' | System | 25 Sep 2020 03:59:32 |



US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6eb92e0a-ebb8-441c-b606-6d2f94069bda' User entered '24 Sep 2020 23:59' | System | 25 Sep 2020 03:59:32 |
|                                                                                                                                                                                                                                                                                                 | System | 25 Sep 2020 03:59:32 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:45:52', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '424d9ee4-c7cf-4cb6-80cf-9b37d4b7c8d6' | System | 18 Sep 2020 15:46:21 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 18 Sep 2020 15:46:21 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '424d9ee4-c7cf-4cb6-80cf-9b37d4b7c8d6' | System | 18 Sep 2020 15:46:21 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 18 Sep 2020 15:46:21 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:10', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '424d9ee4-c7cf-4cb6-80cf-9b37d4b7c8d6' | System | 18 Sep 2020 15:46:21 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 18 Sep 2020 15:46:21 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:16', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '424d9ee4-c7cf-4cb6-80cf-9b37d4b7c8d6' | System | 18 Sep 2020 15:46:21 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 15:46:21 |



US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:18', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '424d9ee4-c7cf-4cb6-80cf-9b37d4b7c8d6' | System | 18 Sep 2020 15:46:21 |
| User entered '18 Sep 2020 11:46'                                                                                                                                                                                                                               | System | 18 Sep 2020 15:46:21 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:34' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 14:04' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 1, after vaccination (at home)' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:42', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cdf8bcc9-99e4-4046-821d-713131af28fb' | System | 19 Sep 2020 00:50:55 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'                                                                                                                                                       | System | 19 Sep 2020 00:50:55 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cdf8bcc9-99e4-4046-821d-713131af28fb' | System | 19 Sep 2020 00:50:55 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Sep 2020 00:50:55 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:47', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cdf8bcc9-99e4-4046-821d-713131af28fb' | System | 19 Sep 2020 00:50:55 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Sep 2020 00:50:55 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:50', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cdf8bcc9-99e4-4046-821d-713131af28fb' | System | 19 Sep 2020 00:50:55 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 00:50:55 |



US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:53', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cdf8bcc9-99e4-4046-821d-713131af28fb' | System | 19 Sep 2020 00:50:55 |
| User entered '18 Sep 2020 20:50'                                                                                                                                                                                                                               | System | 19 Sep 2020 00:50:55 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 14:59' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 2' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '480c77aa-3110-4ec2-923a-102bf5d3265b' | System | 19 Sep 2020 16:54:49 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'                                                                                                                                                       | System | 19 Sep 2020 16:54:49 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '480c77aa-3110-4ec2-923a-102bf5d3265b' | System | 19 Sep 2020 16:54:49 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Sep 2020 16:54:49 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:43', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '480c77aa-3110-4ec2-923a-102bf5d3265b' | System | 19 Sep 2020 16:54:49 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Sep 2020 16:54:49 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '480c77aa-3110-4ec2-923a-102bf5d3265b' | System | 19 Sep 2020 16:54:49 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 16:54:49 |



US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:46', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '480c77aa-3110-4ec2-923a-102bf5d3265b' | System | 19 Sep 2020 16:54:49 |
| User entered '19 Sep 2020 12:54'                                                                                                                                                                                                                               | System | 19 Sep 2020 16:54:49 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 3' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:50', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'aa038c48-491c-409e-a7d7-3ddef7818b3c' | System | 20 Sep 2020 21:04:04 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 20 Sep 2020 21:04:04 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:52', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'aa038c48-491c-409e-a7d7-3ddef7818b3c' | System | 20 Sep 2020 21:04:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Sep 2020 21:04:04 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:54', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'aa038c48-491c-409e-a7d7-3ddef7818b3c' | System | 20 Sep 2020 21:04:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Sep 2020 21:04:04 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:57', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'aa038c48-491c-409e-a7d7-3ddef7818b3c' | System | 20 Sep 2020 21:04:04 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 21:04:04 |



US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:59', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'aa038c48-491c-409e-a7d7-3ddef7818b3c' | System | 20 Sep 2020 21:04:04 |
| User entered '20 Sep 2020 17:03'                                                                                                                                                                                                                               | System | 20 Sep 2020 21:04:04 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 4' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:32', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bb456251-16f5-438f-9fdd-446811fd1ab1' | System | 22 Sep 2020 04:00:47 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 22 Sep 2020 04:00:47 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:34', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bb456251-16f5-438f-9fdd-446811fd1ab1' | System | 22 Sep 2020 04:00:47 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Sep 2020 04:00:47 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:39', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bb456251-16f5-438f-9fdd-446811fd1ab1' | System | 22 Sep 2020 04:00:47 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Sep 2020 04:00:47 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:42', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bb456251-16f5-438f-9fdd-446811fd1ab1' | System | 22 Sep 2020 04:00:47 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 04:00:47 |



US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:44', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bb456251-16f5-438f-9fdd-446811fd1ab1' | System | 22 Sep 2020 04:00:47 |
| User entered '22 Sep 2020 00:00'                                                                                                                                                                                                                               | System | 22 Sep 2020 04:00:47 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 5' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cde116d1-6dbd-4104-9d73-41ef8c3a5f6d' | System | 23 Sep 2020 06:55:39 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 23 Sep 2020 06:55:39 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:31', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cde116d1-6dbd-4104-9d73-41ef8c3a5f6d' | System | 23 Sep 2020 06:55:39 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Sep 2020 06:55:39 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:33', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cde116d1-6dbd-4104-9d73-41ef8c3a5f6d' | System | 23 Sep 2020 06:55:39 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Sep 2020 06:55:39 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:35', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cde116d1-6dbd-4104-9d73-41ef8c3a5f6d' | System | 23 Sep 2020 06:55:39 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 06:55:39 |



US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cde116d1-6dbd-4104-9d73-41ef8c3a5f6d' | System | 23 Sep 2020 06:55:39 |
| User entered '23 Sep 2020 02:55'                                                                                                                                                                                                                               | System | 23 Sep 2020 06:55:39 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 6' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b043ef12-915c-46ed-a9f5-2f3d50a0b4f6' | System | 24 Sep 2020 01:41:48 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 24 Sep 2020 01:41:48 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:39', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b043ef12-915c-46ed-a9f5-2f3d50a0b4f6' | System | 24 Sep 2020 01:41:48 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Sep 2020 01:41:48 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b043ef12-915c-46ed-a9f5-2f3d50a0b4f6' | System | 24 Sep 2020 01:41:48 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Sep 2020 01:41:48 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:43', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b043ef12-915c-46ed-a9f5-2f3d50a0b4f6' | System | 24 Sep 2020 01:41:48 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 24 Sep 2020 01:41:48 |



US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b043ef12-915c-46ed-a9f5-2f3d50a0b4f6' | System | 24 Sep 2020 01:41:48 |
| User entered '23 Sep 2020 21:41'                                                                                                                                                                                                                               | System | 24 Sep 2020 01:41:48 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 7' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ba2b63c5-568b-40d7-b8b7-2d24ba112f0c' | System | 25 Sep 2020 03:59:45 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 25 Sep 2020 03:59:45 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:31', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ba2b63c5-568b-40d7-b8b7-2d24ba112f0c' | System | 25 Sep 2020 03:59:45 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 25 Sep 2020 03:59:45 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:33', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ba2b63c5-568b-40d7-b8b7-2d24ba112f0c' | System | 25 Sep 2020 03:59:45 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 25 Sep 2020 03:59:45 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:34', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ba2b63c5-568b-40d7-b8b7-2d24ba112f0c' | System | 25 Sep 2020 03:59:45 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 25 Sep 2020 03:59:45 |



US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:36', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ba2b63c5-568b-40d7-b8b7-2d24ba112f0c' | System | 25 Sep 2020 03:59:45 |
| User entered '24 Sep 2020 23:59'                                                                                                                                                                                                                               | System | 25 Sep 2020 03:59:45 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:22', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2764e089-6451-44c8-a885-977adb697620' | System | 18 Sep 2020 15:46:53 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 15:46:53 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:24', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2764e089-6451-44c8-a885-977adb697620' | System | 18 Sep 2020 15:46:53 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 15:46:53 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2764e089-6451-44c8-a885-977adb697620' | System | 18 Sep 2020 15:46:53 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 15:46:53 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:29', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2764e089-6451-44c8-a885-977adb697620' | System | 18 Sep 2020 15:46:53 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 15:46:53 |



US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:36', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2764e089-6451-44c8-a885-977adb697620' | System | 18 Sep 2020 15:46:53 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 15:46:53 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:40', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2764e089-6451-44c8-a885-977adb697620' | System | 18 Sep 2020 15:46:53 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 15:46:53 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2764e089-6451-44c8-a885-977adb697620' | System | 18 Sep 2020 15:46:53 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 18 Sep 2020 15:46:53 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:49', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2764e089-6451-44c8-a885-977adb697620' | System | 18 Sep 2020 15:46:53 |
| User entered '18 Sep 2020 11:46'                                                                                                                                                                                                                               | System | 18 Sep 2020 15:46:53 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:34' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 14:04' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 1, after vaccination (at home)' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:58', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6658dfb8-b095-4b8d-9112-c0e729495f7e' | System | 19 Sep 2020 00:51:20 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 19 Sep 2020 00:51:20 |



US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:51:01', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6658dfb8-b095-4b8d-9112-c0e729495f7e' | System | 19 Sep 2020 00:51:20 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 00:51:20 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:51:05', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6658dfb8-b095-4b8d-9112-c0e729495f7e' | System | 19 Sep 2020 00:51:20 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 00:51:20 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:51:07', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6658dfb8-b095-4b8d-9112-c0e729495f7e' | System | 19 Sep 2020 00:51:20 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 00:51:20 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:51:09', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6658dfb8-b095-4b8d-9112-c0e729495f7e' | System | 19 Sep 2020 00:51:20 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 00:51:20 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:51:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6658dfb8-b095-4b8d-9112-c0e729495f7e' | System | 19 Sep 2020 00:51:20 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 00:51:20 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:51:14', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6658dfb8-b095-4b8d-9112-c0e729495f7e' | System | 19 Sep 2020 00:51:20 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Sep 2020 00:51:20 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:51:15', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6658dfb8-b095-4b8d-9112-c0e729495f7e' | System | 19 Sep 2020 00:51:20 |
| User entered '18 Sep 2020 20:51'                                                                                                                                                                                                                               | System | 19 Sep 2020 00:51:20 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 14:59' | System | 18 Sep 2020 15:40:31 |



US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 2' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:50', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c8cd217d-e6f1-4268-a65b-272dcaed2cf2' | System | 19 Sep 2020 16:55:24 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'                                                                                                                                                | System | 19 Sep 2020 16:55:24 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c8cd217d-e6f1-4268-a65b-272dcaed2cf2' | System | 19 Sep 2020 16:55:24 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 19 Sep 2020 16:55:24 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:58', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c8cd217d-e6f1-4268-a65b-272dcaed2cf2' | System | 19 Sep 2020 16:55:24 |
| User entered 'Significant; prevents daily activity (3)'                                                                                                                                                                                                        | System | 19 Sep 2020 16:55:24 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:55:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c8cd217d-e6f1-4268-a65b-272dcaed2cf2' | System | 19 Sep 2020 16:55:24 |
| User entered 'Significant; prevents daily activity (3)'                                                                                                                                                                                                        | System | 19 Sep 2020 16:55:24 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:55:05', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c8cd217d-e6f1-4268-a65b-272dcaed2cf2' | System | 19 Sep 2020 16:55:24 |
| User entered 'Some interference with activity or >2 episodes/24 hours (2)'                                                                                                                                                                                     | System | 19 Sep 2020 16:55:24 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:22:31

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:55:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c8cd217d-e6f1-4268-a65b-272dcaed2cf2' | System | 19 Sep 2020 16:55:24 |
| User entered 'Some interference with activity not requiring medical attention (2)'                                                                                                                                                                             | System | 19 Sep 2020 16:55:24 |



US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:55:15', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c8cd217d-e6f1-4268-a65b-272dcaed2cf2' | System | 19 Sep 2020 16:55:24 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 19 Sep 2020 16:55:24 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:55:20', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c8cd217d-e6f1-4268-a65b-272dcaed2cf2' | System | 19 Sep 2020 16:55:24 |
| User entered '19 Sep 2020 12:55'                                                                                                                                                                                                                               | System | 19 Sep 2020 16:55:24 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 3' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:05', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ecec401d-b023-4c29-9af5-16ea0b8634e1' | System | 20 Sep 2020 21:03:50 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 21:03:50 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ecec401d-b023-4c29-9af5-16ea0b8634e1' | System | 20 Sep 2020 21:03:50 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 20 Sep 2020 21:03:50 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:40', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ecec401d-b023-4c29-9af5-16ea0b8634e1' | System | 20 Sep 2020 21:03:50 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 20 Sep 2020 21:03:50 |



US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ecec401d-b023-4c29-9af5-16ea0b8634e1' | System | 20 Sep 2020 21:03:50 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 20 Sep 2020 21:03:50 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:18', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ecec401d-b023-4c29-9af5-16ea0b8634e1' | System | 20 Sep 2020 21:03:50 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 21:03:50 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:22', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ecec401d-b023-4c29-9af5-16ea0b8634e1' | System | 20 Sep 2020 21:03:50 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 20 Sep 2020 21:03:50 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:25', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ecec401d-b023-4c29-9af5-16ea0b8634e1' User entered 'No (N)' | System | 20 Sep 2020 21:03:50 |
|                                                                                                                                                                                                                                                                                      | System | 20 Sep 2020 21:03:50 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ecec401d-b023-4c29-9af5-16ea0b8634e1' User entered '20 Sep 2020 17:03' | System | 20 Sep 2020 21:03:50 |
|                                                                                                                                                                                                                                                                                                 | System | 20 Sep 2020 21:03:50 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 4' | System | 18 Sep 2020 15:40:31 |



US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a6175b2f-319e-4401-bb67-ff662e39c838' | System | 22 Sep 2020 04:01:14 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 22 Sep 2020 04:01:14 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:50', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a6175b2f-319e-4401-bb67-ff662e39c838' | System | 22 Sep 2020 04:01:14 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 22 Sep 2020 04:01:14 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:53', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a6175b2f-319e-4401-bb67-ff662e39c838' | System | 22 Sep 2020 04:01:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 04:01:14 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:54', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a6175b2f-319e-4401-bb67-ff662e39c838' | System | 22 Sep 2020 04:01:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 04:01:14 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:01:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a6175b2f-319e-4401-bb67-ff662e39c838' | System | 22 Sep 2020 04:01:14 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'                                                                                                                                                                                      | System | 22 Sep 2020 04:01:14 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:01:05', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a6175b2f-319e-4401-bb67-ff662e39c838' | System | 22 Sep 2020 04:01:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 04:01:14 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:01:07', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a6175b2f-319e-4401-bb67-ff662e39c838' | System | 22 Sep 2020 04:01:14 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 22 Sep 2020 04:01:14 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:01:10', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a6175b2f-319e-4401-bb67-ff662e39c838' | System | 22 Sep 2020 04:01:14 |
| User entered '22 Sep 2020 00:01'                                                                                                                                                                                                                               | System | 22 Sep 2020 04:01:14 |



US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 5' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fea74e08-fdd4-481d-b726-2d9a489b85a2' | System | 23 Sep 2020 06:56:05 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 06:56:05 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:44', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fea74e08-fdd4-481d-b726-2d9a489b85a2' | System | 23 Sep 2020 06:56:05 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 23 Sep 2020 06:56:05 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:51', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fea74e08-fdd4-481d-b726-2d9a489b85a2' | System | 23 Sep 2020 06:56:05 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 06:56:05 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:53', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fea74e08-fdd4-481d-b726-2d9a489b85a2' | System | 23 Sep 2020 06:56:05 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 06:56:05 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fea74e08-fdd4-481d-b726-2d9a489b85a2' | System | 23 Sep 2020 06:56:05 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'                                                                                                                                                                                      | System | 23 Sep 2020 06:56:05 |



US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:57', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fea74e08-fdd4-481d-b726-2d9a489b85a2' | System | 23 Sep 2020 06:56:05 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 06:56:05 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:56:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fea74e08-fdd4-481d-b726-2d9a489b85a2' | System | 23 Sep 2020 06:56:05 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Sep 2020 06:56:05 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:56:02', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fea74e08-fdd4-481d-b726-2d9a489b85a2' | System | 23 Sep 2020 06:56:05 |
| User entered '23 Sep 2020 02:56'                                                                                                                                                                                                                               | System | 23 Sep 2020 06:56:05 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 6' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:51', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ac4d297-2993-448a-a72b-0002f2aa7daa' | System | 24 Sep 2020 01:42:17 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'                                                                                                                                                | System | 24 Sep 2020 01:42:17 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ac4d297-2993-448a-a72b-0002f2aa7daa' | System | 24 Sep 2020 01:42:17 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 24 Sep 2020 01:42:17 |



US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:57', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ac4d297-2993-448a-a72b-0002f2aa7daa' | System | 24 Sep 2020 01:42:17 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Sep 2020 01:42:17 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:59', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ac4d297-2993-448a-a72b-0002f2aa7daa' | System | 24 Sep 2020 01:42:17 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Sep 2020 01:42:17 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:42:06', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ac4d297-2993-448a-a72b-0002f2aa7daa' | System | 24 Sep 2020 01:42:17 |
| User entered 'Some interference with activity or >2 episodes/24 hours (2)'                                                                                                                                                                                     | System | 24 Sep 2020 01:42:17 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:42:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ac4d297-2993-448a-a72b-0002f2aa7daa' | System | 24 Sep 2020 01:42:17 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Sep 2020 01:42:17 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:42:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ac4d297-2993-448a-a72b-0002f2aa7daa' | System | 24 Sep 2020 01:42:17 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 24 Sep 2020 01:42:17 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:42:13', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ac4d297-2993-448a-a72b-0002f2aa7daa' | System | 24 Sep 2020 01:42:17 |
| User entered '23 Sep 2020 21:42'                                                                                                                                                                                                                               | System | 24 Sep 2020 01:42:17 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |



US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 18 Sep 2020 15:40:31 |
| User entered 'Day 7' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:40', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '831efed2-845a-4f68-bf31-558134f28e6b' | System | 25 Sep 2020 04:00:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 25 Sep 2020 04:00:14 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:42', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '831efed2-845a-4f68-bf31-558134f28e6b' | System | 25 Sep 2020 04:00:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 25 Sep 2020 04:00:14 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:44', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '831efed2-845a-4f68-bf31-558134f28e6b' | System | 25 Sep 2020 04:00:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 25 Sep 2020 04:00:14 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '831efed2-845a-4f68-bf31-558134f28e6b' | System | 25 Sep 2020 04:00:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 25 Sep 2020 04:00:14 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:47', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '831efed2-845a-4f68-bf31-558134f28e6b' | System | 25 Sep 2020 04:00:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 25 Sep 2020 04:00:14 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '831efed2-845a-4f68-bf31-558134f28e6b' | System | 25 Sep 2020 04:00:14 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 25 Sep 2020 04:00:14 |

US3432229

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:53', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '831efed2-845a-4f68-bf31-558134f28e6b' | System | 25 Sep 2020 04:00:14 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 25 Sep 2020 04:00:14 |



US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:56', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '831efed2-845a-4f68-bf31-558134f28e6b' | System | 25 Sep 2020 04:00:14 |
| User entered '24 Sep 2020 23:59'                                                                                                                                                                                                                               | System | 25 Sep 2020 04:00:14 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 12:00' | System | 18 Sep 2020 15:40:31 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 11:59' | System | 18 Sep 2020 15:40:31 |

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 24 Sep 2020 01:41:48 |
| User entered 'Day 8' | System | 24 Sep 2020 01:41:48 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-26T00:00:07', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '83c14aa5-3644-4104-ae30-07d536c4a23d' | System | 26 Sep 2020 04:00:16 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 26 Sep 2020 04:00:16 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-26T00:00:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '83c14aa5-3644-4104-ae30-07d536c4a23d' | System | 26 Sep 2020 04:00:16 |
| User entered '26 Sep 2020 00:00'                                                                                                                                                                                                                               | System | 26 Sep 2020 04:00:16 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 01:41:48 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 01:41:48 |



US3432229

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 24 Sep 2020 01:41:37 |
| User entered 'Day 8' | System | 24 Sep 2020 01:41:37 |

US3432229

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 09:22:31

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-26T00:00:16', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '97340cda-ab22-4ee8-8bc3-eb9e48dd8063' | System | 26 Sep 2020 04:00:26 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 26 Sep 2020 04:00:26 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-26T00:00:19', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '97340cda-ab22-4ee8-8bc3-eb9e48dd8063' | System | 26 Sep 2020 04:00:26 |
| User entered '26 Sep 2020 00:00'                                                                                                                                                                                                                               | System | 26 Sep 2020 04:00:26 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 01:41:37 |

US3432229

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 09:22:31**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 01:41:37 |

US3432229

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Sep 2020 20:14:12 |
|                        |                  |                      |

US3432229

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '25 Sep 2020' | (b) (4), (b) (6) | 25 Sep 2020 20:14:12 |
|                            |                  |                      |

US3432229

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 25 Sep 2020 20:14:12 |



US3432229

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 20:14:12 |
|                     |                  |                      |

US3432229

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Sep 2020 20:14:24 |
|                        |                  |                      |

US3432229

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Sep 2020 20:14:24 |

US3432229

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 02 Oct 2020 19:09:22 |

US3432229

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '2 Oct 2020' | (b) (4), (b) (6) | 02 Oct 2020 19:09:22 |
|                           |                  |                      |

US3432229

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 02 Oct 2020 19:09:22 |

US3432229

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 02 Oct 2020 19:09:22 |
|                     |                  |                      |

US3432229

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 02 Oct 2020 19:09:27 |
|                        |                  |                      |



US3432229

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 19:09:27 |

US3432229

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Oct 2020 23:20:14 |
|                        |                  |                      |

US3432229

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '9 Oct 2020' | (b) (4), (b) (6) | 09 Oct 2020 23:20:14 |
|                           |                  |                      |

US3432229

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 09 Oct 2020 23:20:14 |

US3432229

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 09 Oct 2020 23:20:14 |
|                     |                  |                      |

US3432229

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Oct 2020 23:20:49 |
|                        |                  |                      |

US3432229

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Oct 2020 23:20:49 |

US3432229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Was this visit performed?](#)

| Audit                                                                                                                                                                                                                                                                                                                                                              | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.<br>' (Site from DM).               | (b) (4), (b) (6)                 | 24 Nov 2020 11:40:37 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.<br>' answered with 'collected' (Site from DM). | Monica Feeley (b) (4)<br>(b) (4) | 10 Nov 2020 21:54:19 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.<br>' (Site from DM).               | (b) (4), (b) (6)                 | 02 Nov 2020 06:14:56 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)                 | 16 Oct 2020 15:51:38 |



US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '16 Oct 2020' | (b) (4), (b) (6) | 16 Oct 2020 15:51:38 |
|                            |                  |                      |

US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'Home (Home)' | (b) (4), (b) (6) | 16 Oct 2020 15:51:38 |
|                            |                  |                      |

US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:22:31**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 16 Oct 2020 15:51:38 |

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Were vital signs assessed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Oct 2020 15:53:18 |
|                        |                  |                      |

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Date of assessment (*dd MMM yyyy*)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '16 Oct 2020' | (b) (4), (b) (6) | 16 Oct 2020 15:53:18 |
|                            |                  |                      |

US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| User entered '11:24' | (b) (4), (b) (6) | 16 Oct 2020 15:53:18 |

US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Oct 2020 11:24' | System | 16 Oct 2020 15:53:18 |

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Temperature (xxx.x)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered '98.7' F | (b) (4), (b) (6) | 16 Oct 2020 15:53:18 |



US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[Route of measurement](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 16 Oct 2020 15:53:18 |

US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[If Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 16 Oct 2020 15:53:18 |

US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[Pulse \(xxx\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| User entered '86' | (b) (4), (b) (6) | 16 Oct 2020 15:53:18 |

US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 16 Oct 2020 15:53:18 |

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| User entered '16' | (b) (4), (b) (6) | 16 Oct 2020 15:53:18 |
|                   |                  |                      |

US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 16 Oct 2020 15:53:18 |

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| User entered '104' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Oct 2020 15:54:20 |
| User entered '105'                                     | (b) (4), (b) (6) | 16 Oct 2020 15:53:18 |

US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 16 Oct 2020 15:53:18 |



US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Diastolic Blood Pressure (xxx)

| Audit                                                                                                                                                                                                        | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).         | (b) (4), (b) (6)      | 16 Nov 2020 13:50:05 |
| Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System). | Monica Feeley (b) (4) | 10 Nov 2020 21:55:13 |
| User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).         | System                | 16 Oct 2020 15:53:18 |
| User entered '58'                                                                                                                                                                                            | (b) (4), (b) (6)      | 16 Oct 2020 15:53:18 |

US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:22:31**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 16 Oct 2020 15:53:18 |

US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:22:31**

[Was the physical examination performed?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 16 Oct 2020 15:54:46 |

US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 16 Oct 2020 15:54:46 |

US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:22:31**

[Was the sample collected?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Monica Feeley (b) (4)<br>(b) (4) | 10 Nov 2020 21:54:51 |

US3432229

**Folder:** Visit 3 Day 57 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 09:22:31

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '16 Oct 2020' | Monica Feeley (b) (4)<br>(b) (4) | 10 Nov 2020 21:54:51 |

US3432229

**Folder:** Visit 3 Day 57 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 09:22:31

[Collection time \(00:00-23:59\)](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '11:39' | Monica Feeley (b) (4)<br>(b) (4) | 10 Nov 2020 21:54:51 |

US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Oct 2020 11:39' | System | 10 Nov 2020 21:54:51 |



US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Oct 2020 15:54:53 |
|                        |                  |                      |

US3432229

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:22:31**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 16 Oct 2020 15:54:53 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 64' | System | 21 Aug 2020 17:08:42 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-23T12:00:19', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '08e519a4-6f70-4d8f-bf84-69cc2eb4aedf' | System | 23 Oct 2020 16:00:42 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Oct 2020 16:00:42 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-23T12:00:23', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '08e519a4-6f70-4d8f-bf84-69cc2eb4aedd' | System | 23 Oct 2020 16:00:42 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Oct 2020 16:00:42 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-23T12:00:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '08e519a4-6f70-4d8f-bf84-69cc2eb4aedf' User entered '23 Oct 2020 12:00:26' | System | 23 Oct 2020 16:00:42 |
|                                                                                                                                                                                                                                                                                                    | System | 23 Oct 2020 16:00:42 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 21 Aug 2020 17:08:42 |
| User entered '21 Oct 2020 00:01' | System | 21 Aug 2020 17:08:42 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 21 Aug 2020 17:08:42 |
| User entered '25 Oct 2020 23:59' | System | 21 Aug 2020 17:08:42 |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 71' | System | 21 Aug 2020 17:08:42 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:15', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' | System | 31 Oct 2020 22:45:34 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 31 Oct 2020 22:45:34 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:17', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' | System | 31 Oct 2020 22:45:34 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 31 Oct 2020 22:45:34 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                                                                 | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered 'Yes (Y)' | System | 31 Oct 2020 22:45:34 |
|                                                                                                                                                                                                                                                                                       | System | 31 Oct 2020 22:45:34 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

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

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0' | System | 31 Oct 2020 22:45:34 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Chills](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' | System | 31 Oct 2020 22:45:34 |
| User entered '0'                                                                                                                                                                                                                                               | System | 31 Oct 2020 22:45:34 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Cough](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' | System | 31 Oct 2020 22:45:34 |
| User entered '0'                                                                                                                                                                                                                                               | System | 31 Oct 2020 22:45:34 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Shortness of breath](#)

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0' | System | 31 Oct 2020 22:45:34 |



US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Difficulty breathing](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' | System | 31 Oct 2020 22:45:34 |
| User entered '0'                                                                                                                                                                                                                                               | System | 31 Oct 2020 22:45:34 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Fatigue](#)

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0' | System | 31 Oct 2020 22:45:34 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Muscle aches](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' | System | 31 Oct 2020 22:45:34 |
| User entered '0'                                                                                                                                                                                                                                               | System | 31 Oct 2020 22:45:34 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Body aches](#)

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0' | System | 31 Oct 2020 22:45:34 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Headache](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' | System | 31 Oct 2020 22:45:34 |
| User entered '0'                                                                                                                                                                                                                                               | System | 31 Oct 2020 22:45:34 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[New loss of taste](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' | System | 31 Oct 2020 22:45:34 |
| User entered '0'                                                                                                                                                                                                                                               | System | 31 Oct 2020 22:45:34 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[New loss of smell](#)

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0' | System | 31 Oct 2020 22:45:34 |
|                                                                                                                                                                                                                                                                                 | System | 31 Oct 2020 22:45:34 |

US3432229

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Sore throat](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' | System | 31 Oct 2020 22:45:34 |
| User entered '1'                                                                                                                                                                                                                                               | System | 31 Oct 2020 22:45:34 |



US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Congestion](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' | System | 31 Oct 2020 22:45:34 |
| User entered '0'                                                                                                                                                                                                                                               | System | 31 Oct 2020 22:45:34 |

US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Runny nose](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' | System | 31 Oct 2020 22:45:34 |
| User entered '0'                                                                                                                                                                                                                                               | System | 31 Oct 2020 22:45:34 |

US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Nausea](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' | System | 31 Oct 2020 22:45:34 |
| User entered '0'                                                                                                                                                                                                                                               | System | 31 Oct 2020 22:45:34 |

US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Vomiting](#)

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0' | System | 31 Oct 2020 22:45:34 |

US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Diarrhea](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' | System | 31 Oct 2020 22:45:34 |
| User entered '0'                                                                                                                                                                                                                                               | System | 31 Oct 2020 22:45:34 |

US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:45:09', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' | System | 31 Oct 2020 22:45:34 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'                                                                                                                                                               | System | 31 Oct 2020 22:45:34 |

US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:45:14', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' | System | 31 Oct 2020 22:45:34 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 31 Oct 2020 22:45:34 |

US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:45:18', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' | System | 31 Oct 2020 22:45:34 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'                                                                                                                                                               | System | 31 Oct 2020 22:45:34 |



US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:45:23', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '31 Oct 2020 18:45:23' | System | 31 Oct 2020 22:45:34 |
|                                                                                                                                                                                                                                                                                                    | System | 31 Oct 2020 22:45:34 |

US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 21 Aug 2020 17:08:42 |
| User entered '28 Oct 2020 00:01' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 21 Aug 2020 17:08:42 |
| User entered '01 Nov 2020 23:59' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 21 Aug 2020 17:08:42 |
| User entered 'Day 78' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-11-08T11:59:13', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6cc877f6-6ab3-4d12-a268-dabf7d64b86a' User entered 'No (N)' | System | 08 Nov 2020 16:59:21 |

US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-11-08T11:59:15', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6cc877f6-6ab3-4d12-a268-dabf7d64b86a' | System | 08 Nov 2020 16:59:21 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Nov 2020 16:59:21 |

US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-11-08T11:59:17', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6cc877f6-6ab3-4d12-a268-dabf7d64b86a' User entered '08 Nov 2020 11:59:17' | System | 08 Nov 2020 16:59:21 |
|                                                                                                                                                                                                                                                                                                    | System | 08 Nov 2020 16:59:21 |

US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 21 Aug 2020 17:08:42 |
| User entered '04 Nov 2020 00:01' | System | 21 Aug 2020 17:08:42 |



US3432229

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 21 Aug 2020 17:08:42 |
| User entered '08 Nov 2020 23:59' | System | 21 Aug 2020 17:08:42 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 61' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '18 Oct 2020 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '22 Oct 2020 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 68' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '25 Oct 2020 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '29 Oct 2020 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 75' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '01 Nov 2020 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '05 Nov 2020 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '08 Nov 2020 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '12 Nov 2020 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '15 Nov 2020 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '19 Nov 2020 23:59' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '22 Nov 2020 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '26 Nov 2020 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 00:32:22 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '29 Nov 2020 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '03 Dec 2020 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '06 Dec 2020 00:01' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '10 Dec 2020 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 00:32:22 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '13 Dec 2020 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '17 Dec 2020 23:59' | System | 20 Nov 2020 00:32:22 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 00:32:22 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '20 Dec 2020 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '24 Dec 2020 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '27 Dec 2020 00:01' | System | 20 Nov 2020 00:32:22 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '31 Dec 2020 23:59' | System | 20 Nov 2020 00:32:22 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '03 Jan 2021 00:01' | System | 20 Nov 2020 00:32:22 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '07 Jan 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 00:32:22 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '10 Jan 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '14 Jan 2021 23:59' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '17 Jan 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '21 Jan 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 00:32:22 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '24 Jan 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '28 Jan 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '31 Jan 2021 00:01' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '04 Feb 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 00:32:22 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '07 Feb 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '11 Feb 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '14 Feb 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '18 Feb 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '21 Feb 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '25 Feb 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '28 Feb 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '04 Mar 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '07 Mar 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '11 Mar 2021 23:59' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '14 Mar 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '18 Mar 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '21 Mar 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '25 Mar 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '28 Mar 2021 00:01' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '01 Apr 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '04 Apr 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '08 Apr 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '11 Apr 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '15 Apr 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '18 Apr 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '22 Apr 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '25 Apr 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '29 Apr 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '02 May 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '06 May 2021 23:59' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '09 May 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '13 May 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '16 May 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '20 May 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '23 May 2021 00:01' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '27 May 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '30 May 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '03 Jun 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '06 Jun 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '10 Jun 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '13 Jun 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '17 Jun 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '20 Jun 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '24 Jun 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '27 Jun 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '01 Jul 2021 23:59' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '04 Jul 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '08 Jul 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '11 Jul 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '15 Jul 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '18 Jul 2021 00:01' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '22 Jul 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '25 Jul 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '29 Jul 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '01 Aug 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '05 Aug 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '08 Aug 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '12 Aug 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '15 Aug 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '19 Aug 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '22 Aug 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '26 Aug 2021 23:59' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '29 Aug 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '02 Sep 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '05 Sep 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '09 Sep 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '12 Sep 2021 00:01' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '16 Sep 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '19 Sep 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '23 Sep 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '26 Sep 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '30 Sep 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '03 Oct 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '07 Oct 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '10 Oct 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '14 Oct 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '17 Oct 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '21 Oct 2021 23:59' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '24 Oct 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '28 Oct 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '31 Oct 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '04 Nov 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '07 Nov 2021 00:01' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '11 Nov 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '14 Nov 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '18 Nov 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '21 Nov 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '25 Nov 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '28 Nov 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '02 Dec 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '05 Dec 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '09 Dec 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '12 Dec 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '16 Dec 2021 23:59' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '19 Dec 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '23 Dec 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '26 Dec 2021 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '30 Dec 2021 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '02 Jan 2022 00:01' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '06 Jan 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '09 Jan 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '13 Jan 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '16 Jan 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '20 Jan 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '23 Jan 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '27 Jan 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '30 Jan 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '03 Feb 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '06 Feb 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '10 Feb 2022 23:59' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '13 Feb 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '17 Feb 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '20 Feb 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '24 Feb 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '27 Feb 2022 00:01' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '03 Mar 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '06 Mar 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '10 Mar 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '13 Mar 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '17 Mar 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '20 Mar 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '24 Mar 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '27 Mar 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '31 Mar 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '03 Apr 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '07 Apr 2022 23:59' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '10 Apr 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '14 Apr 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '17 Apr 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '21 Apr 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '24 Apr 2022 00:01' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '28 Apr 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '01 May 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '05 May 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 09:22:31

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '08 May 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '12 May 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '15 May 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '19 May 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '22 May 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '26 May 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '29 May 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '02 Jun 2022 23:59' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '05 Jun 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '09 Jun 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '12 Jun 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '16 Jun 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '19 Jun 2022 00:01' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '23 Jun 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '26 Jun 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '30 Jun 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '03 Jul 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '07 Jul 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '10 Jul 2022 00:01' | System | 20 Nov 2020 00:32:22 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '14 Jul 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '17 Jul 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '21 Jul 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '24 Jul 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '28 Jul 2022 23:59' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '31 Jul 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '04 Aug 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '07 Aug 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '11 Aug 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '14 Aug 2022 00:01' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '18 Aug 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '21 Aug 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '25 Aug 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '28 Aug 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '01 Sep 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 00:32:22 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '04 Sep 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '08 Sep 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '11 Sep 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '15 Sep 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '18 Sep 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '22 Sep 2022 23:59' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '25 Sep 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '29 Sep 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '02 Oct 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '06 Oct 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '09 Oct 2022 00:01' | System | 20 Nov 2020 00:32:22 |



US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '13 Oct 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '16 Oct 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '20 Oct 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '23 Oct 2022 00:01' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:22:31**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 00:32:22 |
| Amendment Manager: User entered '27 Oct 2022 23:59' | System | 20 Nov 2020 00:32:22 |

US3432229

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Was Contact Attempted?](#)

| Audit                  | User                         | Time (GMT)           |
|------------------------|------------------------------|----------------------|
| User entered 'Yes (Y)' | Phoebe Cunningham<br>(b) (4) | 19 Nov 2020 16:06:57 |



US3432229

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                         | Time (GMT)           |
|----------------------------|------------------------------|----------------------|
| User entered '13 Nov 2020' | Phoebe Cunningham<br>(b) (4) | 19 Nov 2020 16:06:57 |

US3432229

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                         | Time (GMT)           |
|--------------------------------------------|------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Phoebe Cunningham<br>(b) (4) | 19 Nov 2020 16:06:57 |

US3432229

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:22:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                                                                                                                                                             | User                         | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|----------------------|
| User entered 'Called pt. 10NOV2020 a 10:08, 11NOV2020 at 10:00, 12NOV2020 at 10:17, amd 16NOV2020 at 13:52 and 18:34. Left vms at all calls but no contact made.' | Phoebe Cunningham<br>(b) (4) | 19 Nov 2020 16:06:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events Summary

**Generated On:** 26 Nov 2020 09:22:31

[Did the participant experience any adverse events?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 17 Nov 2020 22:19:08 |
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:43:55 |

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Adverse event](#)

| Audit                                                                                                                                                                                                                            | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal disorders NEC, PT: Gastrointestinal disorder, LLT: Gastrointestinal disorder - version MedDRA\\23.0.      | Coder Import (b) (4)<br>(b) (4) | 18 Nov 2020 12:40:04 |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.                                                                                                                                            | Coder Import (b) (4)<br>(b) (4) | 18 Nov 2020 12:40:04 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal signs and symptoms NEC, PT: Abdominal discomfort, LLT: Gastrointestinal upset - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 08 Sep 2020 15:34:51 |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.                                                                                                                                            | Coder Import (b) (4)<br>(b) (4) | 08 Sep 2020 15:34:51 |
| Data point term sent to Coder                                                                                                                                                                                                    | System                          | 08 Sep 2020 13:44:56 |
| User entered 'transient gastrointestinal illness'                                                                                                                                                                                | Xhoi Mitre (b) (4)<br>(b) (4)   | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Was this a medically-attended AE?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |



US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '04 Sep 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Start time \(00:00-23:59\)](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Ongoing?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '05 Sep 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[End time \(00:00-23:59\)](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 13:44:55 |

US3432229

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Severity](#)

| Audit                                      | User                          | Time (GMT)           |
|--------------------------------------------|-------------------------------|----------------------|
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |



US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Is the adverse event serious?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Death](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Life threatening](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Admitted to ICU?](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Number of Days in ICU](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |



US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Other medically important event](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Relationship to investigational product](#)

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Relationship to Study Procedure](#)

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Action taken with investigational product](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'None (NONE)' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[None](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Concomitant Medication](#)

| Audit                                                                                                                                                                                                                                                                                                        | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per CDM: Response noted, however the Indication for Conmed Zofran does not match the term for this AE. Please review and reconcile data.' (Site from DM).                                                                                                                                 | (b) (4), (b) (6)      | 23 Nov 2020 04:22:04 |
| Query 'Per CDM: Response noted, however the Indication for Conmed Zofran does not match the term for this AE. Please review and reconcile data.' answered with 'updated' (Site from DM).                                                                                                                     | Monica Feeley (b) (4) | 10 Nov 2020 22:03:45 |
| User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).                                   | (b) (4), (b) (6)      | 10 Nov 2020 10:27:08 |
| User opened query 'Per CDM: Response noted, however the Indication for Conmed Zofran does not match the term for this AE. Please review and reconcile data.' (Site from DM).                                                                                                                                 | (b) (4), (b) (6)      | 10 Nov 2020 10:27:06 |
| Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'please see zofran in con meds' (Site from DM). | Monica Feeley (b) (4) | 20 Oct 2020 16:04:58 |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).                                   | (b) (4), (b) (6)      | 02 Oct 2020 02:08:55 |
| User entered '1'                                                                                                                                                                                                                                                                                             | Xhoi Mitre (b) (4)    | 08 Sep 2020 13:44:55 |



US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Concomitant Procedure](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Outcome](#)

| Audit                                                  | User               | Time (GMT)           |
|--------------------------------------------------------|--------------------|----------------------|
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Xhoi Mitre (b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Narrative](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 08 Sep 2020 13:44:55 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:22:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 08 Sep 2020 13:44:55 |

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:22:31

[Adverse event](#)

| Audit                                                                                                                                                                                                                                        | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 11 Sep 2020 21:15:44 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                                 | Coder Import (b) (4)<br>(b) (4) | 11 Sep 2020 21:15:44 |
| Data point term sent to Coder                                                                                                                                                                                                                | System                          | 11 Sep 2020 21:14:36 |
| User entered 'Sore Throat'                                                                                                                                                                                                                   | Xhoi Mitre (b) (4)<br>(b) (4)   | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Was this a medically-attended AE?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |



US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '10 Sep 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Start time \(00:00-23:59\)](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Ongoing?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

If not Ongoing, end date (*dd MMM yyyy*)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '10 Sep 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[End time \(00:00-23:59\)](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |



US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Severity](#)

| Audit                                      | User                          | Time (GMT)           |
|--------------------------------------------|-------------------------------|----------------------|
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Is the adverse event serious?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Death](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Life threatening](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |



US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Admitted to ICU?](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Number of Days in ICU](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Other medically important event](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Relationship to investigational product](#)

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Relationship to Study Procedure](#)

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Action taken with investigational product](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'None (NONE)' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |



US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[None](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '1' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Concomitant Medication](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Concomitant Procedure](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Outcome](#)

| Audit                                                  | User                          | Time (GMT)           |
|--------------------------------------------------------|-------------------------------|----------------------|
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Narrative](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 11 Sep 2020 21:13:57 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:22:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 11 Sep 2020 21:13:57 |



US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:22:31

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 20 Oct 2020 19:08:45 |
| User entered<br>'USA-US078-2020-mRNA-1273-P301000007' | System           | 20 Oct 2020 19:08:39 |
| User entered 'New'                                    | (b) (4), (b) (6) | 20 Oct 2020 19:08:39 |

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:22:31

[Adverse event](#)

| Audit                                                                                                                                                                                                                                | User                            | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as SOC: Psychiatric disorders, HLGT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Intentional self-injury, LLT: Self injurious behavior - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 20 Oct 2020 04:59:33 |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.                                                                                                                                                | Coder Import (b) (4)<br>(b) (4) | 20 Oct 2020 04:59:33 |
| Data point term sent to Coder                                                                                                                                                                                                        | System                          | 20 Oct 2020 00:50:50 |
| User entered 'Self- Injurious behavior'                                                                                                                                                                                              | Xhoi Mitre (b) (4)<br>(b) (4)   | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Was this a medically-attended AE?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '17 Oct 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Start time \(00:00-23:59\)](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Oct 2020 00:50:18 |



US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Ongoing?](#)

| Audit                                                    | User                  | Time (GMT)           |
|----------------------------------------------------------|-----------------------|----------------------|
| User entered 'No (N)' reason for change: New Information | Monica Feeley (b) (4) | 06 Nov 2020 13:24:53 |
| User entered 'Yes (Y)'                                   | Xhoi Mitre (b) (4)    | 20 Oct 2020 00:50:18 |

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                   | User                  | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).             | (b) (4), (b) (6)      | 09 Nov 2020 12:37:03 |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety). | Monica Feeley (b) (4) | 06 Nov 2020 13:25:07 |
| User entered '30 Oct 2020' reason for change: New Information                                                                                                                                                           | Monica Feeley (b) (4) | 06 Nov 2020 13:24:53 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).             | (b) (4), (b) (6)      | 29 Oct 2020 21:19:55 |
| User entered empty.                                                                                                                                                                                                     | Xhoi Mitre (b) (4)    | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[End time \(00:00-23:59\)](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Oct 2020 00:50:18 |

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:22:31

[Severity](#)

| Audit                                                                                                                                                                                                                 | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).                                                          | (b) (4), (b) (6)      | 09 Nov 2020 12:37:09 |
| Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'this is grade three as this was not life threatening' (Site from Safety). | Monica Feeley (b) (4) | 06 Nov 2020 13:31:55 |
| User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).                                                          | (b) (4), (b) (6)      | 29 Oct 2020 21:21:29 |
| User entered 'Grade 3/Severe (Grade 3/Severe)'                                                                                                                                                                        | Xhoi Mitre (b) (4)    | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Is the adverse event serious?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Death](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Life threatening](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |



US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                                                                                                                                                                                                                                                                                                                  | User                | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).                                                                              | (b) (4), (b) (6)    | 06 Nov 2020 08:18:45 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'currently hospitalized at time of data entry. admission date is provided' (Site from System). | Bruce Bausk (b) (4) | 24 Oct 2020 13:26:11 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).                                                                              | System              | 24 Oct 2020 13:25:00 |
| User entered '1' reason for change: Data Entry Error                                                                                                                                                                                                                                                                   | Bruce Bausk (b) (4) | 24 Oct 2020 13:25:00 |
| User entered '0'                                                                                                                                                                                                                                                                                                       | Xhoi Mitre (b) (4)  | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit                                                         | User                | Time (GMT)           |
|---------------------------------------------------------------|---------------------|----------------------|
| User entered '24 Oct 2020' reason for change: New Information | Bruce Bausk (b) (4) | 24 Oct 2020 13:25:00 |
| User entered empty.                                           | Xhoi Mitre (b) (4)  | 20 Oct 2020 00:50:18 |

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:22:31

Hospital Discharge Date (dd MMM yyyy)

| Audit                                                                                                                    | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).             | (b) (4), (b) (6)      | 09 Nov 2020 12:37:15 |
| Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety). | Monica Feeley (b) (4) | 06 Nov 2020 13:25:27 |
| User entered '30 Oct 2020' reason for change: New Information                                                            | Monica Feeley (b) (4) | 06 Nov 2020 13:24:53 |
| User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).             | (b) (4), (b) (6)      | 29 Oct 2020 21:19:37 |
| User entered empty.                                                                                                      | Xhoi Mitre (b) (4)    | 20 Oct 2020 00:50:18 |

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:22:31

[Admitted to ICU?](#)

| Audit                                                                                                                                                                                                   | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per CDM: A response is needed for this field. Please update the field accordingly. Note: A response UNKNOWN can be recorded till the data is available.' (Site from DM).             | (b) (4), (b) (6)      | 09 Nov 2020 06:43:11 |
| Query 'Per CDM: A response is needed for this field. Please update the field accordingly. Note: A response UNKNOWN can be recorded till the data is available.' answered with 'updated' (Site from DM). | Monica Feeley (b) (4) | 06 Nov 2020 13:25:31 |
| User entered 'No (N)' reason for change: New Information                                                                                                                                                | Monica Feeley (b) (4) | 06 Nov 2020 13:24:53 |
| User opened query 'Per CDM: A response is needed for this field. Please update the field accordingly. Note: A response UNKNOWN can be recorded till the data is available.' (Site from DM).             | (b) (4), (b) (6)      | 06 Nov 2020 08:21:17 |
| User entered empty.                                                                                                                                                                                     | Xhoi Mitre (b) (4)    | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Number of Days in ICU](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Other medically important event](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '1' | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |



US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Relationship to investigational product](#)

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Relationship to Study Procedure](#)

| Audit                                    | User                          | Time (GMT)           |
|------------------------------------------|-------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Action taken with investigational product](#)

| Audit                                          | User                          | Time (GMT)           |
|------------------------------------------------|-------------------------------|----------------------|
| User entered 'Not Applicable (NOT APPLICABLE)' | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:22:31

None

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Please verify if treatments were given for this SAE as it required hospitalization and treatments may have been given. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM).                                                                                                                                                                                   | (b) (4), (b) (6)      | 09 Nov 2020 06:44:00 |
| Query 'Per DM CLR: Please verify if treatments were given for this SAE as it required hospitalization and treatments may have been given. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' answered with 'no treatments as of now. This is a psychological condition, treatments in the form of medication and procedures are not necessarily provided. Will update if anything changes' (Site from DM). | Monica Feeley (b) (4) | 29 Oct 2020 13:51:17 |
| User opened query 'Per DM CLR: Please verify if treatments were given for this SAE as it required hospitalization and treatments may have been given. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM).                                                                                                                                                                                   | (b) (4), (b) (6)      | 28 Oct 2020 23:03:29 |
| User entered '1'                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Xhoi Mitre (b) (4)    | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Concomitant Medication](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Concomitant Procedure](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:22:31

[Outcome](#)

| Audit                                                                                                                                                                                                                                                | User                  | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).             | (b) (4), (b) (6)      | 09 Nov 2020 12:37:22 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety). | Monica Feeley (b) (4) | 06 Nov 2020 13:25:34 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information                                                                                                                                                            | Monica Feeley (b) (4) | 06 Nov 2020 13:24:53 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).             | (b) (4), (b) (6)      | 29 Oct 2020 21:20:14 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'                                                                                                                                                                               | Xhoi Mitre (b) (4)    | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 20 Oct 2020 00:50:18 |



US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:22:31

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).                                                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)                 | 09 Nov 2020 12:37:33 |
| User closed query 'PV Query: Please assess if history of psychiatry hospitalization last in 2017 for suicidal ideation should be added to medical history.' (Site from Safety).                                                                                                                                                                                                                                                                                                                  | (b) (4), (b) (6)                 | 09 Nov 2020 12:37:31 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)                 | 09 Nov 2020 12:37:30 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).                                                                                                                              | (b) (4), (b) (6)                 | 09 Nov 2020 12:37:28 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'receiving repetitive transcranial magnetic stimulation (rTMS) daily starting 29OCT2020. Currently ongoing as outpatient.' (Site from Safety). | Monica Feeley (b) (4)<br>(b) (4) | 06 Nov 2020 13:38:33 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with '18OCT2020 COVID-19 NP swab- negative 23Oct2020 COVID-19 NP swab- negative ' (Site from Safety).                                                                                                                                                                                         | Monica Feeley (b) (4)<br>(b) (4) | 06 Nov 2020 13:36:09 |

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:22:31

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                               | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no relevant laboratory results as this was a psychiatric admission<br />' (Site from Safety).                                                                                                         | Monica Feeley (b) (4) | 06 Nov 2020 13:31:07 |
| Query 'PV Query: Please assess if history of psychiatry hospitalization last in 2017 for suicidal ideation should be added to medical history.' answered with 'already captured as medical history, see mood disorder' (Site from Safety).                                                                                                                          | Monica Feeley (b) (4) | 06 Nov 2020 13:30:45 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).                                                                                                                                                                                      | (b) (4), (b) (6)      | 29 Oct 2020 21:21:13 |
| User opened query 'PV Query: Please assess if history of psychiatry hospitalization last in 2017 for suicidal ideation should be added to medical history.' (Site from Safety).                                                                                                                                                                                     | (b) (4), (b) (6)      | 29 Oct 2020 21:21:03 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).                                                                                                                                           | (b) (4), (b) (6)      | 29 Oct 2020 21:20:41 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6)      | 29 Oct 2020 21:20:28 |

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:22:31

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | User                | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User entered 'PARTICIPANT PRESENTED TO THE ED ON 17OCT2020 FOR SELF-INJURIOUS BEHAVIOR. HAS HISTORY OF PSYCHIATRY HOSPITALIZATION ( LAST IN 2017 FOR SUICIDAL IDEATION). CURRENT EPISODE IS THOUGHT TO BE AN EXACERBATION OF TRAUMA THEY EXPERIENCED. STAYED IN ED 17-18 OCT. AND WAS TRANSFERRED TO A COMMUNITY CRISIS STABILIZATION UNIT. TRIED TO CALL PARTICIPANT TODAY, NO ANSWER. WILL FOLLOW UP. <br /><br />24Oct20 - Pt re-consulted in ED for self-injurious behavior. Symptomatology and assessment are similar to previous ED visit on 17Oct2020. Because of recent failure of CCS level of care, pt is hospitalized for current episode. Admitted this morning.' reason for change: New Information | Bruce Bausk (b) (4) | 24 Oct 2020 13:25:00 |
| User entered 'Participant presented to the ED on 17OCT2020 for self-injurious behavior. Has history of psychiatry hospitalization ( last in 2017 for suicidal ideation). Current episode is thought to be an exacerbation of trauma they experienced. Stayed in ED 17-18 Oct. and was transferred to a community crisis stabilization unit. Tried to call participant today, No answer. Will follow up. '                                                                                                                                                                                                                                                                                                        | Xhoi Mitre (b) (4)  | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Oct 2020 00:50:18 |

US3432229

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:22:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 06 Nov 2020 13:24:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 09:22:31**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:10:41 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                     | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: LISDEXAMFETAMINE MESILATE, PRODUCTSYNONYM: VYVANSE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 21 Aug 2020 22:13:22 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                 | Coder Import (b) (4) | 21 Aug 2020 22:13:22 |
| Data point term sent to Coder                                                                                                                                                                                                                                             | System               | 21 Aug 2020 22:12:41 |
| User entered 'vyvanse'                                                                                                                                                                                                                                                    | Xhoi Mitre (b) (4)   | 21 Aug 2020 22:12:03 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Prophylaxis](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:03 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Indication](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered 'ADHD' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:03 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose per administration](#)

| Audit             | User                          | Time (GMT)           |
|-------------------|-------------------------------|----------------------|
| User entered '40' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:03 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose unit](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'mg (mg)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:03 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

If dose unit is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:03 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Frequency](#)

| Audit                          | User                          | Time (GMT)           |
|--------------------------------|-------------------------------|----------------------|
| User entered 'once daily (QD)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:03 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

[If frequency is Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:03 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Route of administration](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:03 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

If route of administration is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:03 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'UN UNK 2016' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:03 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:03 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Ongoing?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:03 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:03 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Was this medication taken for solicited event?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:03 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 22:12:03 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 22:12:03 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 22:12:03 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                    | User                            | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 23 Aug 2020 19:18:42 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.                                                                                                                       | Coder Import (b) (4)<br>(b) (4) | 23 Aug 2020 19:18:42 |
| Data point term sent to Coder                                                                                                                                                                                            | System                          | 21 Aug 2020 22:13:43 |
| User entered 'Wellbutrin'                                                                                                                                                                                                | Xhoi Mitre (b) (4)<br>(b) (4)   | 21 Aug 2020 22:12:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Prophylaxis](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Indication](#)

| Audit                        | User                          | Time (GMT)           |
|------------------------------|-------------------------------|----------------------|
| User entered 'Mood Disorder' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose per administration](#)

| Audit              | User                          | Time (GMT)           |
|--------------------|-------------------------------|----------------------|
| User entered '450' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose unit](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'mg (mg)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

If dose unit is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Frequency](#)

| Audit                          | User                          | Time (GMT)           |
|--------------------------------|-------------------------------|----------------------|
| User entered 'once daily (QD)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:53 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

[If frequency is Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Route of administration](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

If route of administration is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'UN Feb 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Ongoing?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Was this medication taken for solicited event?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 21 Aug 2020 22:12:53 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 22:12:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 22:12:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 22:12:53 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                                                           | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 21 Aug 2020 22:19:29 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                                                                       | Coder Import (b) (4)<br>(b) (4) | 21 Aug 2020 22:19:29 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                   | System                          | 21 Aug 2020 22:18:50 |
| User entered 'Symbicort'                                                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)<br>(b) (4)     | 21 Aug 2020 22:18:13 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 22:18:13 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Indication](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'Asthma' | (b) (4), (b) (6) | 21 Aug 2020 22:18:13 |
|                       |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose per administration](#)

| Audit                                                                                                                                                                                                                                                                                                          | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puff/s. Please verify the dose and unit, and update as appropriate.<br>' (Site from DM).                                                | (b) (4), (b) (6)      | 23 Nov 2020 07:43:38 |
| Query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puff/s. Please verify the dose and unit, and update as appropriate.<br>' answered with 'unknown. this is what participant provided' (Site from DM). | Monica Feeley (b) (4) | 10 Nov 2020 21:46:26 |
| User opened query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puff/s. Please verify the dose and unit, and update as appropriate.<br>' (Site from DM).                                                | (b) (4), (b) (6)      | 03 Nov 2020 06:19:06 |
| User entered '2'                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)      | 21 Aug 2020 22:18:13 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose unit](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'puff (PUFF)' | (b) (4), (b) (6) | 21 Aug 2020 22:18:13 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

If dose unit is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 22:18:13 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Frequency](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| User entered 'twice daily (BID)' | (b) (4), (b) (6) | 21 Aug 2020 22:18:13 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 22:18:13 |
|                     |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Route of administration](#)

| Audit                                                                 | User             | Time (GMT)           |
|-----------------------------------------------------------------------|------------------|----------------------|
| User entered 'Respiratory (Inhalation)<br>(RESPIRATORY (INHALATION))' | (b) (4), (b) (6) | 21 Aug 2020 22:18:13 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 22:18:13 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'un Feb 2020' | (b) (4), (b) (6) | 21 Aug 2020 22:18:13 |
|                            |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 22:18:13 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 22:18:13 |
|                        |                  |                      |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 22:18:13 |
|                     |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 22:18:13 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 21 Aug 2020 22:18:13 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 22:18:13 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 22:18:13 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                          | User                            | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLOVENT - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 21 Aug 2020 22:21:16 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                      | Coder Import (b) (4)<br>(b) (4) | 21 Aug 2020 22:21:16 |
| Data point term sent to Coder                                                                                                                                                                                                                                                  | System                          | 21 Aug 2020 22:20:55 |
| User entered 'Flovent'                                                                                                                                                                                                                                                         | (b) (4), (b) (6)                | 21 Aug 2020 22:20:26 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 22:20:26 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Indication](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'Asthma' | (b) (4), (b) (6) | 21 Aug 2020 22:20:26 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose per administration](#)

| Audit                                                                                                                                                                                                                                                                                                                         | User                  | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.<br>' (Site from DM).                                                            | (b) (4), (b) (6)      | 23 Nov 2020 07:43:45 |
| Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.<br>' answered with 'unknown. This is information that participant provided' (Site from DM). | Monica Feeley (b) (4) | 10 Nov 2020 21:50:35 |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.<br>' (Site from DM).                                                            | (b) (4), (b) (6)      | 03 Nov 2020 06:21:03 |
| User entered '2'                                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6)      | 21 Aug 2020 22:20:26 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose unit](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'puff (PUFF)' | (b) (4), (b) (6) | 21 Aug 2020 22:20:26 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

If dose unit is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 22:20:26 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Frequency](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| User entered 'twice daily (BID)' | (b) (4), (b) (6) | 21 Aug 2020 22:20:26 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 22:20:26 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Route of administration](#)

| Audit                                                                 | User             | Time (GMT)           |
|-----------------------------------------------------------------------|------------------|----------------------|
| User entered 'Respiratory (Inhalation)<br>(RESPIRATORY (INHALATION))' | (b) (4), (b) (6) | 21 Aug 2020 22:20:26 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 22:20:26 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'un Jun 2019' | (b) (4), (b) (6) | 21 Aug 2020 22:20:26 |
|                            |                  |                      |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 22:20:26 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Ongoing?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 22:20:26 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'un Jun 2020' | (b) (4), (b) (6) | 21 Aug 2020 22:20:26 |
|                            |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 22:20:26 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 21 Aug 2020 22:20:26 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 22:20:26 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 22:20:26 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                      | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 21 Aug 2020 22:23:18 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                  | Coder Import (b) (4)<br>(b) (4) | 21 Aug 2020 22:23:18 |
| Data point term sent to Coder                                                                                                                                                                                                                                              | System                          | 21 Aug 2020 22:22:57 |
| User entered 'Albuterol'                                                                                                                                                                                                                                                   | (b) (4), (b) (6)<br>(b) (4)     | 21 Aug 2020 22:22:27 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 22:22:27 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Indication](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'Asthma' | (b) (4), (b) (6) | 21 Aug 2020 22:22:27 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose per administration](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '2' | (b) (4), (b) (6) | 21 Aug 2020 22:22:27 |
|                  |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose unit](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'puff (PUFF)' | (b) (4), (b) (6) | 21 Aug 2020 22:22:27 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

If dose unit is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 22:22:27 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 21 Aug 2020 22:22:27 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 22:22:27 |
|                     |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Route of administration](#)

| Audit                                                                 | User             | Time (GMT)           |
|-----------------------------------------------------------------------|------------------|----------------------|
| User entered 'Respiratory (Inhalation)<br>(RESPIRATORY (INHALATION))' | (b) (4), (b) (6) | 21 Aug 2020 22:22:27 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 22:22:27 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '21 Aug 2020' | (b) (4), (b) (6) | 21 Aug 2020 22:22:27 |
|                            |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 22:22:27 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 22:22:27 |
|                        |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 22:22:27 |
|                     |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 22:22:27 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 22:22:27 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 22:22:27 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 22:22:27 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                         | User                            | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 22 Aug 2020 04:44:32 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.                                                                                                                                            | Coder Import (b) (4)<br>(b) (4) | 22 Aug 2020 04:44:32 |
| Data point term sent to Coder                                                                                                                                                                                                                 | System                          | 21 Aug 2020 22:23:58 |
| User entered 'Testosterone'                                                                                                                                                                                                                   | (b) (4), (b) (6)<br>(b) (4)     | 21 Aug 2020 22:23:57 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 22:23:57 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

[Indication](#)

| Audit                                                                                                                                                                                                                                                    | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Query 'Per DM CLR: Please update INDICATION to include the actual medical condition the med is being used to prevent/treat. Please review and update accordingly.<br>' answered with 'used by participant for "general health" purposes' (Site from DM). | Monica Feeley (b) (4) | 20 Oct 2020 16:06:02 |
| User opened query 'Per DM CLR: Please update INDICATION to include the actual medical condition the med is being used to prevent/treat. Please review and update accordingly.<br>' (Site from DM).                                                       | (b) (4), (b) (6)      | 01 Oct 2020 09:11:56 |
| User entered 'general health'                                                                                                                                                                                                                            | (b) (4), (b) (6)      | 21 Aug 2020 22:23:57 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose per administration](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| User entered '40' | (b) (4), (b) (6) | 21 Aug 2020 22:23:57 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'mg (mg)' | (b) (4), (b) (6) | 21 Aug 2020 22:23:57 |
|                        |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

If dose unit is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 22:23:57 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

[Frequency](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| User entered 'other (OTHER)' | (b) (4), (b) (6) | 21 Aug 2020 22:23:57 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

[If frequency is Other, specify](#)

| Audit                             | User             | Time (GMT)           |
|-----------------------------------|------------------|----------------------|
| User entered 'once every 9 weeks' | (b) (4), (b) (6) | 21 Aug 2020 22:23:57 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

[Route of administration](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| User entered 'Subcutaneous (SUBCUTANEOUS)' | (b) (4), (b) (6) | 21 Aug 2020 22:23:57 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 22:23:57 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'un Nov 2019' | (b) (4), (b) (6) | 21 Aug 2020 22:23:57 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 22:23:57 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 22:23:57 |
|                        |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 22:23:57 |
|                     |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 22:23:57 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 22:23:57 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 22:23:57 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 22:23:57 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                               | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: OXICAMS, PRODUCT:<br>MELOXICAM - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Sep 2020 22:02:36 |
| User coded data point as Term Coded data point by<br>User: (b) (6) version<br>WHODrug-Global-B3\\202003.                                                                                                                                                            | Coder Import (b) (4)<br>(b) (4) | 06 Sep 2020 22:02:36 |
| Data point term sent to Coder                                                                                                                                                                                                                                       | System                          | 05 Sep 2020 14:21:43 |
| User entered 'Meloxicam'                                                                                                                                                                                                                                            | Phoebe Cunningham<br>(b) (4)    | 05 Sep 2020 14:20:45 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

[Prophylaxis](#)

| Audit                 | User                         | Time (GMT)           |
|-----------------------|------------------------------|----------------------|
| User entered 'No (N)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:20:45 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

[Indication](#)

| Audit                           | User                         | Time (GMT)           |
|---------------------------------|------------------------------|----------------------|
| User entered 'Menstrual cramps' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:20:45 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose per administration](#)

| Audit                                                                                                                                                                                                                                           | User                      | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).                                    | (b) (4), (b) (6)          | 10 Nov 2020 10:13:38 |
| Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'dosage reported by participant' (Site from DM). | Monica Feeley (b) (4)     | 20 Oct 2020 16:06:31 |
| User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).                                    | (b) (4), (b) (6)          | 03 Oct 2020 06:15:33 |
| User entered '14'                                                                                                                                                                                                                               | Phoebe Cunningham (b) (4) | 05 Sep 2020 14:20:45 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose unit](#)

| Audit                  | User                         | Time (GMT)           |
|------------------------|------------------------------|----------------------|
| User entered 'mg (mg)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:20:45 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

If dose unit is Other, specify

| Audit               | User                         | Time (GMT)           |
|---------------------|------------------------------|----------------------|
| User entered empty. | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:20:45 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

[Frequency](#)

| Audit                          | User                         | Time (GMT)           |
|--------------------------------|------------------------------|----------------------|
| User entered 'once daily (QD)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:20:45 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

[If frequency is Other, specify](#)

| Audit               | User                         | Time (GMT)           |
|---------------------|------------------------------|----------------------|
| User entered empty. | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:20:45 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

[Route of administration](#)

| Audit                      | User                         | Time (GMT)           |
|----------------------------|------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:20:45 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

If route of administration is Other, specify

| Audit               | User                         | Time (GMT)           |
|---------------------|------------------------------|----------------------|
| User entered empty. | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:20:45 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                         | Time (GMT)           |
|----------------------------|------------------------------|----------------------|
| User entered '22 Aug 2020' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:20:45 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User                         | Time (GMT)           |
|------------------|------------------------------|----------------------|
| User entered '0' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:20:45 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

[Ongoing?](#)

| Audit                 | User                         | Time (GMT)           |
|-----------------------|------------------------------|----------------------|
| User entered 'No (N)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:20:45 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                         | Time (GMT)           |
|----------------------------|------------------------------|----------------------|
| User entered '23 Aug 2020' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:20:45 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

[Was this medication taken for solicited event?](#)

| Audit                 | User                         | Time (GMT)           |
|-----------------------|------------------------------|----------------------|
| User entered 'No (N)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:20:45 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Sep 2020 14:20:45 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Sep 2020 14:20:45 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Sep 2020 14:20:45 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                               | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STERIODS, ATC: OXICAMS, PRODUCT:<br>MELOXICAM - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Sep 2020 22:03:36 |
| User coded data point as Term Coded data point by<br>User: (b) (6) version<br>WHODrug-Global-B3\\202003.                                                                                                                                                            | Coder Import (b) (4)<br>(b) (4) | 06 Sep 2020 22:03:36 |
| Data point term sent to Coder                                                                                                                                                                                                                                       | System                          | 05 Sep 2020 14:22:44 |
| User entered 'Meloxicam'                                                                                                                                                                                                                                            | Phoebe Cunningham<br>(b) (4)    | 05 Sep 2020 14:22:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

[Prophylaxis](#)

| Audit                 | User                         | Time (GMT)           |
|-----------------------|------------------------------|----------------------|
| User entered 'No (N)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:22:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

[Indication](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | User                      | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).                  | (b) (4), (b) (6)          | 06 Nov 2020 08:26:02 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'no ae needed' (Site from DM). | Monica Feeley (b) (4)     | 20 Oct 2020 16:06:53 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).                  | (b) (4), (b) (6)          | 03 Oct 2020 06:16:19 |
| User entered 'headache'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Phoebe Cunningham (b) (4) | 05 Sep 2020 14:22:43 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose per administration](#)

| Audit                                                                                                                                                                                                                                           | User                      | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).                                    | (b) (4), (b) (6)          | 10 Nov 2020 10:15:19 |
| Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'dosage reported by participant' (Site from DM). | Monica Feeley (b) (4)     | 20 Oct 2020 16:07:31 |
| User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).                                    | (b) (4), (b) (6)          | 03 Oct 2020 06:16:10 |
| User entered '14'                                                                                                                                                                                                                               | Phoebe Cunningham (b) (4) | 05 Sep 2020 14:22:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose unit](#)

| Audit                  | User                         | Time (GMT)           |
|------------------------|------------------------------|----------------------|
| User entered 'mg (mg)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:22:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

If dose unit is Other, specify

| Audit               | User                         | Time (GMT)           |
|---------------------|------------------------------|----------------------|
| User entered empty. | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:22:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

[Frequency](#)

| Audit                          | User                         | Time (GMT)           |
|--------------------------------|------------------------------|----------------------|
| User entered 'once daily (QD)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:22:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

[If frequency is Other, specify](#)

| Audit               | User                         | Time (GMT)           |
|---------------------|------------------------------|----------------------|
| User entered empty. | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:22:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

[Route of administration](#)

| Audit                      | User                         | Time (GMT)           |
|----------------------------|------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:22:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

If route of administration is Other, specify

| Audit               | User                         | Time (GMT)           |
|---------------------|------------------------------|----------------------|
| User entered empty. | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:22:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date \(dd MMM yyyy\)](#)

| Audit                                                                                                                                                                                                                                                                                                                               | User                      | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| User closed query 'Per DM CLR: Please review Start date of this medication as this is after the occurrence of Headache which started 26 Aug 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' (Site from DM).                                                  | (b) (4), (b) (6)          | 23 Nov 2020 07:44:12 |
| Query 'Per DM CLR: Please review Start date of this medication as this is after the occurrence of Headache which started 26 Aug 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' answered with 'headache occurred on 27AUG2020 as per diary?' (Site from DM). | Monica Feeley (b) (4)     | 10 Nov 2020 21:51:54 |
| User opened query 'Per DM CLR: Please review Start date of this medication as this is after the occurrence of Headache which started 26 Aug 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' (Site from DM).                                                  | (b) (4), (b) (6)          | 03 Nov 2020 07:48:33 |
| User entered '27 Aug 2020'                                                                                                                                                                                                                                                                                                          | Phoebe Cunningham (b) (4) | 05 Sep 2020 14:22:43 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User                         | Time (GMT)           |
|------------------|------------------------------|----------------------|
| User entered '0' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:22:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

[Ongoing?](#)

| Audit                 | User                         | Time (GMT)           |
|-----------------------|------------------------------|----------------------|
| User entered 'No (N)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:22:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                         | Time (GMT)           |
|----------------------------|------------------------------|----------------------|
| User entered '27 Aug 2020' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:22:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

[Was this medication taken for solicited event?](#)

| Audit                  | User                         | Time (GMT)           |
|------------------------|------------------------------|----------------------|
| User entered 'Yes (Y)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:22:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Sep 2020 14:22:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Sep 2020 14:22:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Sep 2020 14:22:43 |

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                               | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: OXICAMS, PRODUCT:<br>MELOXICAM - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Sep 2020 22:03:36 |
| User coded data point as Term Coded data point by<br>User: (b) (6) version<br>WHODrug-Global-B3\\202003.                                                                                                                                                            | Coder Import (b) (4)<br>(b) (4) | 06 Sep 2020 22:03:36 |
| Data point term sent to Coder                                                                                                                                                                                                                                       | System                          | 05 Sep 2020 14:26:49 |
| User entered 'Meloxicam'                                                                                                                                                                                                                                            | Phoebe Cunningham<br>(b) (4)    | 05 Sep 2020 14:26:14 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

[Prophylaxis](#)

| Audit                 | User                         | Time (GMT)           |
|-----------------------|------------------------------|----------------------|
| User entered 'No (N)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:26:14 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

[Indication](#)

| Audit                                                                                                                                                                                                                                                           | User                      | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| User closed query 'Per DM CLR: Please note there is no MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH/ AE eCRF.' (Site from DM).           | (b) (4), (b) (6)          | 10 Nov 2020 10:22:51 |
| Query 'Per DM CLR: Please note there is no MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH/ AE eCRF.' answered with 'no AE' (Site from DM). | Monica Feeley (b) (4)     | 20 Oct 2020 16:07:41 |
| User opened query 'Per DM CLR: Please note there is no MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH/ AE eCRF.' (Site from DM).           | (b) (4), (b) (6)          | 03 Oct 2020 06:16:42 |
| User entered 'headache'                                                                                                                                                                                                                                         | Phoebe Cunningham (b) (4) | 05 Sep 2020 14:26:14 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose per administration](#)

| Audit                                                                                                                                                                                                                                           | User                      | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).                                    | (b) (4), (b) (6)          | 10 Nov 2020 10:28:51 |
| Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'dosage reported by participant' (Site from DM). | Monica Feeley (b) (4)     | 20 Oct 2020 16:07:45 |
| User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).                                    | (b) (4), (b) (6)          | 03 Oct 2020 06:16:38 |
| User entered '14'                                                                                                                                                                                                                               | Phoebe Cunningham (b) (4) | 05 Sep 2020 14:26:14 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose unit](#)

| Audit                  | User                         | Time (GMT)           |
|------------------------|------------------------------|----------------------|
| User entered 'mg (mg)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:26:14 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

If dose unit is Other, specify

| Audit               | User                         | Time (GMT)           |
|---------------------|------------------------------|----------------------|
| User entered empty. | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:26:14 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

[Frequency](#)

| Audit                      | User                         | Time (GMT)           |
|----------------------------|------------------------------|----------------------|
| User entered 'once (ONCE)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:26:14 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

[If frequency is Other, specify](#)

| Audit               | User                         | Time (GMT)           |
|---------------------|------------------------------|----------------------|
| User entered empty. | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:26:14 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

[Route of administration](#)

| Audit                      | User                         | Time (GMT)           |
|----------------------------|------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:26:14 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

If route of administration is Other, specify

| Audit               | User                         | Time (GMT)           |
|---------------------|------------------------------|----------------------|
| User entered empty. | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:26:14 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                         | Time (GMT)           |
|----------------------------|------------------------------|----------------------|
| User entered '28 Aug 2020' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:26:14 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User                         | Time (GMT)           |
|------------------|------------------------------|----------------------|
| User entered '0' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:26:14 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

[Ongoing?](#)

| Audit                 | User                         | Time (GMT)           |
|-----------------------|------------------------------|----------------------|
| User entered 'No (N)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:26:14 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                         | Time (GMT)           |
|----------------------------|------------------------------|----------------------|
| User entered '28 Aug 2020' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:26:14 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

[Was this medication taken for solicited event?](#)

| Audit                 | User                         | Time (GMT)           |
|-----------------------|------------------------------|----------------------|
| User entered 'No (N)' | Phoebe Cunningham<br>(b) (4) | 05 Sep 2020 14:26:14 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Sep 2020 14:26:14 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Sep 2020 14:26:14 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Sep 2020 14:26:14 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

[Name of Medication](#)

| Audit                                                                                                                                                                                               | User                            | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: SODIUM, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 19 Sep 2020 09:09:53 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.                                                                                                  | Coder Import (b) (4)<br>(b) (4) | 19 Sep 2020 09:09:53 |
| Data point term sent to Coder                                                                                                                                                                       | System                          | 18 Sep 2020 16:15:33 |
| User entered 'Sodium chloride'                                                                                                                                                                      | Bruce Bausk (b) (4)<br>(b) (4)  | 18 Sep 2020 16:14:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:14:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

[Indication](#)

| Audit                                  | User                           | Time (GMT)           |
|----------------------------------------|--------------------------------|----------------------|
| User entered 'orthostatic pre-syncopy' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:14:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose per administration](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '1' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:14:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose unit](#)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| User entered 'g (g)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:14:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

If dose unit is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:14:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

[Frequency](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'once daily (QD)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:14:34 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:14:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:14:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:14:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '25 Aug 2020' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:14:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:14:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

[Ongoing?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:14:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:14:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Bruce Bausk (b) (4)<br>(b) (4) | 18 Sep 2020 16:14:34 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 16:14:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 16:14:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Sep 2020 16:14:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

[Name of Medication](#)

| Audit                                                                                                                                                                                                    | User                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 25 Sep 2020 20:10:49 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                | Coder Import (b) (4) | 25 Sep 2020 20:10:49 |
| Data point term sent to Coder                                                                                                                                                                            | System               | 25 Sep 2020 20:10:14 |
| User entered 'Tylenol'                                                                                                                                                                                   | (b) (4), (b) (6)     | 25 Sep 2020 20:09:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 20:09:43 |
|                       |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

[Indication](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES did not meet the AE reporting criteria.<br>' (Site from DM).           | (b) (4), (b) (6)      | 23 Nov 2020 07:45:47 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES did not meet the AE reporting criteria.<br>' answered with 'no AE' (Site from DM). | Monica Feeley (b) (4) | 10 Nov 2020 21:52:09 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

[Indication](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES did not meet the AE reporting criteria.<br />' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 07:32:12 |
| User entered 'Headaches, pain at injection site, muscle aches'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Sep 2020 20:09:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered '1000' | (b) (4), (b) (6) | 25 Sep 2020 20:09:43 |
|                     |                  |                      |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'mg (mg)' | (b) (4), (b) (6) | 25 Sep 2020 20:09:43 |
|                        |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

If dose unit is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 20:09:43 |
|                     |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

[Frequency](#)

| Audit                                  | User             | Time (GMT)           |
|----------------------------------------|------------------|----------------------|
| User entered 'three times daily (TID)' | (b) (4), (b) (6) | 25 Sep 2020 20:09:43 |
|                                        |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 20:09:43 |
|                     |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 25 Sep 2020 20:09:43 |
|                            |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 20:09:43 |
|                     |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '19 Sep 2020' | (b) (4), (b) (6) | 25 Sep 2020 20:09:43 |
|                            |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 25 Sep 2020 20:09:43 |
|                  |                  |                      |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

[Ongoing?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 20:09:43 |
|                       |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '20 Sep 2020' | (b) (4), (b) (6) | 25 Sep 2020 20:09:43 |
|                            |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

[Was this medication taken for solicited event?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Sep 2020 20:09:43 |
|                        |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 25 Sep 2020 20:09:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Sep 2020 20:09:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 25 Sep 2020 20:09:43 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                  | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: IBUPROFEN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 27 Sep 2020 09:35:34 |
| User coded data point as Term Coded data point by<br>User: (b) (6) version<br>WHODrug-Global-B3\\202003.                                                                                                                                                                               | Coder Import (b) (4)<br>(b) (4) | 27 Sep 2020 09:35:34 |
| Data point term sent to Coder                                                                                                                                                                                                                                                          | System                          | 25 Sep 2020 20:13:28 |
| User entered 'Ibuprofen'                                                                                                                                                                                                                                                               | (b) (4), (b) (6)                | 25 Sep 2020 20:12:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 20:12:34 |
|                       |                  |                      |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

[Indication](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES did not meet the AE reporting criteria.<br>' (Site from DM).           | (b) (4), (b) (6)      | 23 Nov 2020 07:45:53 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES did not meet the AE reporting criteria.<br>' answered with 'no AE' (Site from DM). | Monica Feeley (b) (4) | 10 Nov 2020 21:52:18 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

[Indication](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES did not meet the AE reporting criteria.<br />' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 07:59:05 |
| User entered 'Headaches, pain at injection site, muscle aches.'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | (b) (4), (b) (6) | 25 Sep 2020 20:12:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose per administration](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| User entered '600' | (b) (4), (b) (6) | 25 Sep 2020 20:12:34 |
|                    |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'mg (mg)' | (b) (4), (b) (6) | 25 Sep 2020 20:12:34 |
|                        |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

If dose unit is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 20:12:34 |
|                     |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

[Frequency](#)

| Audit                                  | User             | Time (GMT)           |
|----------------------------------------|------------------|----------------------|
| User entered 'three times daily (TID)' | (b) (4), (b) (6) | 25 Sep 2020 20:12:34 |
|                                        |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 20:12:34 |
|                     |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 25 Sep 2020 20:12:34 |
|                            |                  |                      |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 20:12:34 |
|                     |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '19 Sep 2020' | (b) (4), (b) (6) | 25 Sep 2020 20:12:34 |
|                            |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 25 Sep 2020 20:12:34 |
|                  |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

[Ongoing?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Sep 2020 20:12:34 |
|                       |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '20 Sep 2020' | (b) (4), (b) (6) | 25 Sep 2020 20:12:34 |
|                            |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

[Was this medication taken for solicited event?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Sep 2020 20:12:34 |
|                        |                  |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 25 Sep 2020 20:12:34 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Sep 2020 20:12:34 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 25 Sep 2020 20:12:34 |

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:22:31

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                     | User                             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 11 Nov 2020 04:41:48 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.                                                                                                                                                                        | Coder Import (b) (4)<br>(b) (4)  | 11 Nov 2020 04:41:48 |
| Data point term sent to Coder                                                                                                                                                                                                                                             | System                           | 10 Nov 2020 22:04:58 |
| Coding entries removed.                                                                                                                                                                                                                                                   | Monica Feeley (b) (4)<br>(b) (4) | 10 Nov 2020 22:04:09 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 06 Oct 2020 15:26:27 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.                                                                                                                                                                        | Coder Import (b) (4)<br>(b) (4)  | 06 Oct 2020 15:26:27 |
| Data point term sent to Coder                                                                                                                                                                                                                                             | System                           | 06 Oct 2020 14:56:16 |
| User entered 'Zofran'                                                                                                                                                                                                                                                     | Xhoi Mitre (b) (4)<br>(b) (4)    | 06 Oct 2020 14:55:28 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

[Prophylaxis](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 06 Oct 2020 14:55:28 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

[Indication](#)

| Audit                                             | User                  | Time (GMT)           |
|---------------------------------------------------|-----------------------|----------------------|
| User entered 'transient gastrointestinal illness' | Monica Feeley (b) (4) | 10 Nov 2020 22:04:09 |
| reason for change: Per Query Resolution           | (b) (4)               |                      |
| User entered 'Nausea/ vomiting'                   | Xhoi Mitre (b) (4)    | 06 Oct 2020 14:55:28 |
|                                                   | (b) (4)               |                      |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose per administration](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '4' | Xhoi Mitre (b) (4)<br>(b) (4) | 06 Oct 2020 14:55:28 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

[Dose unit](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'mg (mg)' | Xhoi Mitre (b) (4)<br>(b) (4) | 06 Oct 2020 14:55:28 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

If dose unit is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 06 Oct 2020 14:55:28 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

[Frequency](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'once (ONCE)' | Xhoi Mitre (b) (4)<br>(b) (4) | 06 Oct 2020 14:55:28 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

[If frequency is Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 06 Oct 2020 14:55:28 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

[Route of administration](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Xhoi Mitre (b) (4)<br>(b) (4) | 06 Oct 2020 14:55:28 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

If route of administration is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Xhoi Mitre (b) (4)<br>(b) (4) | 06 Oct 2020 14:55:28 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '04 Sep 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 06 Oct 2020 14:55:28 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

[Start date completely unknown](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Xhoi Mitre (b) (4)<br>(b) (4) | 06 Oct 2020 14:55:28 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

[Ongoing?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 06 Oct 2020 14:55:28 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '04 Sep 2020' | Xhoi Mitre (b) (4)<br>(b) (4) | 06 Oct 2020 14:55:28 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

[Was this medication taken for solicited event?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Xhoi Mitre (b) (4)<br>(b) (4) | 06 Oct 2020 14:55:28 |



US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 14:55:28 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 14:55:28 |

US3432229

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:22:31**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Oct 2020 14:55:28 |

US3432229

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 09:22:31**

[Were any concomitant procedures performed?](#)

| Audit                                                     | User               | Time (GMT)           |
|-----------------------------------------------------------|--------------------|----------------------|
| User entered 'Yes (Y)' reason for change: New Information | (b) (4), (b) (6)   | 10 Oct 2020 18:16:28 |
| User entered 'No (N)' reason for change: Data Entry Error | Xhoi Mitre (b) (4) | 21 Aug 2020 22:10:35 |
| User entered 'Yes (Y)'                                    | Xhoi Mitre (b) (4) | 21 Aug 2020 22:10:14 |

US3432229

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:22:31**

**Procedure/Surgery date (*dd MMM yyyy*)**

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '2 Oct 2020' | (b) (4), (b) (6) | 10 Oct 2020 18:16:43 |
|                           |                  |                      |

US3432229

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Procedure/Surgery](#)

| Audit                                                                                       | User                | Time (GMT)           |
|---------------------------------------------------------------------------------------------|---------------------|----------------------|
| User entered 'RTMS (Transcranial magnetic stimulation)' reason for change: Data Entry Error | Bruce Bausk (b) (4) | 10 Oct 2020 18:19:04 |
| User entered 'RTMS'                                                                         | (b) (4), (b) (6)    | 10 Oct 2020 18:16:43 |

US3432229

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:22:31**

[Indication](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| User entered 'Medical History (MH)' | (b) (4), (b) (6) | 10 Oct 2020 18:16:43 |
|                                     |                  |                      |

US3432229

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:22:31**

[If indication is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 10 Oct 2020 18:16:43 |
|                     |                  |                      |



US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered<br>'USA-US078-2020-MRNA-1273-P301000007' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'Yes (Y)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 26 Oct 2020 16:01:02 |
| Un-reviewed for Safety. | System           | 24 Oct 2020 13:25:00 |
| User entered 'Yes (Y)'  | System           | 24 Oct 2020 13:25:00 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)'   | System           | 20 Oct 2020 19:08:39 |

US3432229

**Folder:** SAE USA-US078-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)' | System           | 20 Oct 2020 19:08:39 |

US3432229

**Folder:** SAE USA-US078-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'Yes (Y)' | System           | 20 Oct 2020 19:08:39 |



US3432229

**Folder:** SAE USA-US078-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:22:31

[Investigator's First Name](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'Lindsey' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's Last Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'Baden' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'MA'    | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Oct 2020 19:09:22 |
| User entered 'US'    | System           | 20 Oct 2020 19:09:15 |

US3432229

**Folder:** SAE USA-US078-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:22:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 09 Nov 2020 12:37:51 |
| User entered '2' | System | 26 Oct 2020 16:01:13 |
| User entered '1' | System | 20 Oct 2020 19:09:15 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered<br>'USA-US078-2020-MRNA-1273-P301000007' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'Yes (Y)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)' | System           | 20 Oct 2020 19:08:39 |



US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 26 Oct 2020 16:01:02 |
| Un-reviewed for Safety. | System           | 24 Oct 2020 13:25:00 |
| User entered 'Yes (Y)'  | System           | 24 Oct 2020 13:25:00 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)'   | System           | 20 Oct 2020 19:08:39 |

US3432229

**Folder:** SAE USA-US078-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'Yes (Y)' | System           | 20 Oct 2020 19:08:39 |

US3432229

**Folder:** SAE USA-US078-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:22:31

[Investigator's First Name](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'Lindsey' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's Last Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'Baden' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'MA'    | System           | 20 Oct 2020 19:08:39 |



US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Oct 2020 19:09:22 |
| User entered 'US'    | System           | 20 Oct 2020 19:09:15 |

US3432229

**Folder:** SAE USA-US078-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:22:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 09 Nov 2020 12:37:51 |
| User entered '2' | System | 26 Oct 2020 16:01:13 |
| User entered '1' | System | 20 Oct 2020 19:09:15 |

US3432229

**Folder:** SAE USA-US078-2020-MRNA-1273-P301000007

**Form:** Safety Report Form (1)

**Generated On:** 26 Nov 2020 09:22:31

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| User entered '20/Oct/2020 19:09' | System           | 20 Oct 2020 19:09:15 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:22:31

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Oct 2020 19:09:22 |
| User entered '1'     | (b) (4), (b) (6) | 20 Oct 2020 19:09:15 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered<br>'USA-US078-2020-MRNA-1273-P301000007' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'Yes (Y)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)' | System           | 20 Oct 2020 19:08:39 |



US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 26 Oct 2020 16:01:02 |
| Un-reviewed for Safety. | System           | 24 Oct 2020 13:25:00 |
| User entered 'Yes (Y)'  | System           | 24 Oct 2020 13:25:00 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)'   | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'Yes (Y)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's First Name](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'Lindsey' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's Last Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'Baden' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'MA'    | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Oct 2020 19:09:22 |
| User entered 'US'    | System           | 20 Oct 2020 19:09:15 |



US3432229

**Folder:** SAE USA-US078-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:22:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 09 Nov 2020 12:37:51 |
| User entered '2' | System | 26 Oct 2020 16:01:13 |
| User entered '1' | System | 20 Oct 2020 19:09:15 |

US3432229

**Folder:** SAE USA-US078-2020-MRNA-1273-P301000007

**Form:** Safety Report Form (2)

**Generated On:** 26 Nov 2020 09:22:31

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| User entered '26/Oct/2020 16:01' | System           | 26 Oct 2020 16:01:13 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:22:31

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Nov 2020 12:37:44 |
| User entered '1'     | (b) (4), (b) (6) | 26 Oct 2020 16:01:13 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered<br>'USA-US078-2020-MRNA-1273-P301000007' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'Yes (Y)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 26 Oct 2020 16:01:02 |
| Un-reviewed for Safety. | System           | 24 Oct 2020 13:25:00 |
| User entered 'Yes (Y)'  | System           | 24 Oct 2020 13:25:00 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)'   | System           | 20 Oct 2020 19:08:39 |



US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'No (N)' | System           | 20 Oct 2020 19:08:39 |

US3432229

**Folder:** SAE USA-US078-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:22:31

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'Yes (Y)' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's First Name](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'Lindsey' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's Last Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'Baden' | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Oct 2020 19:09:03 |
| User entered 'MA'    | System           | 20 Oct 2020 19:08:39 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Oct 2020 19:09:22 |
| User entered 'US'    | System           | 20 Oct 2020 19:09:15 |

US3432229

**Folder:** SAE USA-US078-2020-MRNA-1273-P301000007

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:22:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 09 Nov 2020 12:37:51 |
| User entered '2' | System | 26 Oct 2020 16:01:13 |
| User entered '1' | System | 20 Oct 2020 19:09:15 |



US3432229

**Folder:** SAE USA-US078-2020-MRNA-1273-P301000007

**Form:** Safety Report Form (3)

**Generated On:** 26 Nov 2020 09:22:31

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| User entered '09/Nov/2020 07:37' | System           | 09 Nov 2020 12:37:51 |

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:22:31

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 22:19:00 |
| User entered '1'    | (b) (4), (b) (6) | 09 Nov 2020 12:37:51 |