

US3732262 (Prod: eStudySite - La Mesa - PPDS)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:12:45

All time stamps listed in this document are displayed in GMT

US3732262

**Form: Participant Creation**

**Generated On: 26 Nov 2020 11:12:45**

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[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:12:45

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:45

|                                           |                                                                                                                                                                            |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy)                  | (b) (6) 1983                                                                                                                                                               |
| Age                                       | 37                                                                                                                                                                         |
| Age Units                                 | YEARS                                                                                                                                                                      |
| Age (Derived)                             | 37                                                                                                                                                                         |
| Sex                                       | Female <input checked="" type="radio"/><br>Male <input type="radio"/>                                                                                                      |
| Ethnicity                                 | Hispanic or Latino <input checked="" type="radio"/><br>Not Hispanic or Latino <input type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |                                                                                                                                                                            |
| White                                     | True                                                                                                                                                                       |
| Black                                     | False                                                                                                                                                                      |
| Asian                                     | False                                                                                                                                                                      |
| American Indian or Alaska Native          | False                                                                                                                                                                      |
| Native Hawaiian or other Pacific Islander | False                                                                                                                                                                      |
| Other                                     | False                                                                                                                                                                      |
| If race is Other, specify _____           |                                                                                                                                                                            |
| Unknown                                   | False                                                                                                                                                                      |
| Not reported                              | False                                                                                                                                                                      |

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:12:45

|                                                 |                                              |
|-------------------------------------------------|----------------------------------------------|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 02 SEP 2020                                  |
| Month and Year of Informed Consent (derived)    | SEP 2020                                     |
| Year of Informed Consent (derived)              | 2020                                         |
| Protocol Version                                | Amendment 1 <input type="radio"/>            |
|                                                 | Amendment 2 <input type="radio"/>            |
|                                                 | Amendment 3 <input checked="" type="radio"/> |
|                                                 | Amendment 4 <input type="radio"/>            |
|                                                 | Amendment 5 <input type="radio"/>            |
| Was participant enrolled in the study?          | Yes <input checked="" type="radio"/>         |
|                                                 | No <input type="radio"/>                     |
| If No, indicate reason for screen fail          | Withdrew Consent <input type="radio"/>       |
|                                                 | Inclusion/Exclusion <input type="radio"/>    |
|                                                 | Cohort Full <input type="radio"/>            |
|                                                 | Other <input type="radio"/>                  |
| If reason for screen fail is Other, specify     |                                              |
| Was this participant screened previously?       | Yes <input type="radio"/>                    |
|                                                 | No <input checked="" type="radio"/>          |
| If Yes, previous participant number             |                                              |
| Enrollment Trigger                              | 1                                            |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:12:45

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

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|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | ENVIRONMENTAL ALLERGIES                                          |
| Start date (dd MMM yyyy)                          | UN UNK 1996                                                      |
| 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 1996                                                         |
| Start Year (derived)                              | 1996                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:45

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | MYOPIA                                                           |
| Start date (dd MMM yyyy)                          | UN UNK 1996                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2010                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 1996                                                         |
| Start Year (derived)                              | 1996                                                             |
| Stop Month and Year (derived)                     | JAN 2010                                                         |
| Stop Year (derived)                               | 2010                                                             |

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:45

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | ASTIGMATISM                                                      |
| Start date (dd MMM yyyy)                          | UN UNK 1996                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2010                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 1996                                                         |
| Start Year (derived)                              | 1996                                                             |
| Stop Month and Year (derived)                     | JAN 2010                                                         |
| Stop Year (derived)                               | 2010                                                             |

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:45

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

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Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:45

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | CONSTIPATION                                                     |
| Start date (dd MMM yyyy)                                | UN UNK 1989                                                      |
| 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 1989                                                         |
| Start Year (derived)                                    | 1989                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |

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Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:45

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | UNCOMPLICATED URINARY<br>TRACT INFECTION                         |
| Start date (dd MMM yyyy)                          | UN UNK 2014                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2014                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2014                                                         |
| Start Year (derived)                              | 2014                                                             |
| Stop Month and Year (derived)                     | JAN 2014                                                         |
| Stop Year (derived)                               | 2014                                                             |

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:12:45

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | IRON DEFICIENCY ANEMIA                                           |
| Start date (dd MMM yyyy)                          | UN UNK 1998                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 1999                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 1998                                                         |
| Start Year (derived)                              | 1998                                                             |
| Stop Month and Year (derived)                     | JAN 1999                                                         |
| Stop Year (derived)                               | 1999                                                             |

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:12:45

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | MIGRAINE HEADACHES                                               |
| Start date (dd MMM yyyy)                          | UN UNK 2017                                                      |
| 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 2017                                                         |
| Start Year (derived)                              | 2017                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:12:45

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | POST-PARTUM DEPRESSION                                           |
| Start date (dd MMM yyyy)                          | UN UNK 2014                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2014                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2014                                                         |
| Start Year (derived)                              | 2014                                                             |
| Stop Month and Year (derived)                     | JAN 2014                                                         |
| Stop Year (derived)                               | 2014                                                             |



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Form: Medical History (10)

Generated On: 26 Nov 2020 11:12:45

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | ANXIETY                                                          |
| Start date (dd MMM yyyy)                                | UN UNK 2014                                                      |
| 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 2014                                                         |
| Start Year (derived)                                    | 2014                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |

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Form: Medical History (11)

Generated On: 26 Nov 2020 11:12:45

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | HUMAN PAPILLOMAVIRUS                                             |
| Start date (dd MMM yyyy)                          | UN UNK 2019                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2019                                                         |
| Start Year (derived)                              | 2019                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Form: Medical History (12)

Generated On: 26 Nov 2020 11:12:45

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

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:12:45

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

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:12:45

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | HYPERTENSION                                                     |
| Start date (dd MMM yyyy)                                | UN UNK 2014                                                      |
| 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 2014                                                         |
| Start Year (derived)                                    | 2014                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:12:45

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

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:12:45

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | MENSTRUAL CRAMPS                                                 |
| Start date (dd MMM yyyy)                          | UN UNK 2014                                                      |
| 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 2014                                                         |
| Start Year (derived)                              | 2014                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

|                                           |                                      |
|-------------------------------------------|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|                                           | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 02 SEP 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 15:09 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 02 SEP 2020 15:09                    |
| Height ( <i>xxx.x</i> )                   | 161.6 cm                             |
| Weight ( <i>xxx.x</i> )                   | 81.2 kg                              |
| BMI ( <i>xxx.x</i> )                      | 31.09377 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 11:12:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:12:45

Date of assessment (*dd MMM yyyy*) 02 SEP 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

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|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| Was the pregnancy test performed?   | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of test ( <i>dd MMM yyyy</i> ) | 02 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)  |                                           |

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Folder: Screening

Form: Risk of Exposure

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#### 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 checked="" type="radio"/> |
|                                                                                                                                                         | No <input type="radio"/>             |
| <b>Hospitality and Tourism Workers</b> (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)                                          | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Pastoral, Social or Public Health Workers</b> requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Educators and Students</b> (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)                  | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Other</b>                                                                                                                                            | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |

#### Specify

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

|                                                                                                                                              |       |
|----------------------------------------------------------------------------------------------------------------------------------------------|-------|
| <b>No Risk Identified</b>                                                                                                                    | False |
| <b>Resides in Nursing Home or Assisted Living Facility</b>                                                                                   | False |
| <b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) | False |

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Folder: Screening

Form: Risk of Exposure

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:45

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 02 SEP 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | VISIT1                                  |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:45

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

What was the participant's randomization number? 111299

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 11:12:45

|        |               |
|--------|---------------|
| 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 11:12:45

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 02 SEP 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 15:09 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 02 SEP 2020 15:09                                                                                      |
| Temperature (xxx.x)                 | 99.0 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 95 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 14 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 136 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 85 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:45

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 02 SEP 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 16:47 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 02 SEP 2020 16:47                                                                                      |
| Temperature (xxx.x)                 | 100.5 F                                                                                                |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 92 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 16 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 122 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 93 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

US3732262

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:45

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.*

US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:12:45

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) \_\_\_\_\_

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:45

|                                                                                                              |                                                      |
|--------------------------------------------------------------------------------------------------------------|------------------------------------------------------|
| Was study treatment given?                                                                                   | Yes <input checked="" type="radio"/>                 |
|                                                                                                              | No <input type="radio"/>                             |
| If No, reason not given                                                                                      | Participant declined due to <input type="radio"/>    |
|                                                                                                              | Adverse Event <input type="radio"/>                  |
|                                                                                                              | Physician withheld dose due to <input type="radio"/> |
|                                                                                                              | 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 <input type="radio"/>       |
|                                                                                                              | 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)                                                                   | 02 SEP 2020                                          |
| What was the treatment time? (00:00-23:59)                                                                   | 16:17 (24 HR)                                        |
| Treatment Date and Time (derived)                                                                            | 02 SEP 2020 16:17                                    |
| 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                                        |

US3732262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:45

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 02 SEP 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 15:59 (24 HR)                        |
| Collection date and time (derived)     | 02 SEP 2020 15:59                    |

US3732262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:12:45

| Collection date ( <i>dd MMM yyyy</i> ) |                           |                                          | 02 SEP 2020                        |
|----------------------------------------|---------------------------|------------------------------------------|------------------------------------|
| Lab Test                               | Was the sample collected? | Collection time ( <i>00:00 - 23:59</i> ) | Collection date and time (derived) |
| Nasopharyngeal Swab 1                  | Yes                       | 15:38                                    | 02 SEP 2020 15:38                  |
| Nasopharyngeal Swab 2                  | No                        |                                          |                                    |

US3732262

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

**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

100.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 16:53

PC Open Date & Time

02 SEP 2020 16:37

PC Close Date & Time

02 SEP 2020 19:07

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

**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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 02 SEP 2020 22:23

PC Open Date & Time 02 SEP 2020 20:02

PC Close Date & Time 03 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:12:45

**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

99.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 12:03

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:12:45

**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               | 98.1 °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        | 04 SEP 2020 16:03 |
| PC Open Date & Time  | 04 SEP 2020 12:00 |
| PC Close Date & Time | 05 SEP 2020 11:59 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 19:16

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:12:45

**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

99.0 °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

06 SEP 2020 13:24

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:12:45

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

07 SEP 2020 16:37

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:12:45

**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

98.6 °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

08 SEP 2020 17:22

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59



US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 16:55

PC Open Date & Time

02 SEP 2020 16:37

PC Close Date & Time

02 SEP 2020 19:07

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 22:25

PC Open Date & Time

02 SEP 2020 20:02

PC Close Date & Time

03 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:12:45

**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

03 SEP 2020 12:46

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 16:05

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:12:45

**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

05 SEP 2020 19:17

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 13:24

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 16:37

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:12:45

**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

08 SEP 2020 13:32

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59



US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

**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 ☐

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 02 SEP 2020 16:56 |
| PC Open Date & Time  | 02 SEP 2020 16:37 |
| PC Close Date & Time | 02 SEP 2020 19:07 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

**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 ☐

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 02 SEP 2020 22:28 |
| PC Open Date & Time  | 02 SEP 2020 20:02 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:12:45

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 ☒

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:12:45

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 03 SEP 2020 12:47 |
| PC Open Date & Time          | 03 SEP 2020 12:00 |
| PC Close Date & Time         | 04 SEP 2020 11:59 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:12:45

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 ☒

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:12:45

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 SEP 2020 16:08 |
| PC Open Date & Time          | 04 SEP 2020 12:00 |
| PC Close Date & Time         | 05 SEP 2020 11:59 |



US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:12:45

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 ☒

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:12:45

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 05 SEP 2020 19:18 |
| PC Open Date & Time          | 05 SEP 2020 12:00 |
| PC Close Date & Time         | 06 SEP 2020 11:59 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:12:45

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 ☒

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:12:45

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 SEP 2020 13:25 |
| PC Open Date & Time          | 06 SEP 2020 12:00 |
| PC Close Date & Time         | 07 SEP 2020 11:59 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:12:45

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 ☒

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:12:45

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 07 SEP 2020 16:38 |
| PC Open Date & Time          | 07 SEP 2020 12:00 |
| PC Close Date & Time         | 08 SEP 2020 11:59 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:12:45

**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 ☒

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:12:45

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 08 SEP 2020 13:33 |
| PC Open Date & Time          | 08 SEP 2020 12:00 |
| PC Close Date & Time         | 09 SEP 2020 11:59 |



US3732262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732262

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:45

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

VISIT WILL BE OMITTED DUE  
TO CONVALESCENT PERIOD.

*If Contact Not Made, please provide Comments*

US3732262

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:45

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

SUBJECT WAS IN THE  
CONVALESCENT PHASE

If Contact Not Made, please provide Comments

US3732262

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:45

|                           |                                     |
|---------------------------|-------------------------------------|
| Was this visit performed? | Yes <input type="radio"/>           |
|                           | No <input checked="" type="radio"/> |

|                          |  |
|--------------------------|--|
| Visit date (dd MMM yyyy) |  |
|--------------------------|--|

|                                                                 |                              |
|-----------------------------------------------------------------|------------------------------|
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>   |
|                                                                 | Clinic <input type="radio"/> |

|            |        |
|------------|--------|
| Folder OID | VISIT2 |
|------------|--------|

US3732262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:45

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



US3732262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:45

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

US3732262

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:45

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.***

US3732262

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:12:45

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

US3732262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:12:45

Was study treatment given? Yes ☐  
No ☐

If No, reason not given

Participant declined due to ☐  
Adverse Event ☐  
Physician withheld dose due to ☐  
Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by ☐  
Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? \_\_\_\_\_

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

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

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

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

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

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

US3732262

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:45

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

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

US3732262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:12:45

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

US3732262

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:45

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

SUBJECT WAS IN THE  
CONVALESCENT PHASE

If Contact Not Made, please provide Comments



US3732262

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732262

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:45

Was Contact Attempted?

Yes ☒

No ☐

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

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732262

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:45

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 04 NOV 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | VISIT3                                  |

US3732262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

|                                           |                                       |
|-------------------------------------------|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|                                           | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 04 NOV 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 14:38 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 04 NOV 2020 14:38                     |
| Temperature ( <i>xxx.x</i> )              | 99.2 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> )    | 134 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 88 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3732262

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 NOV 2020

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



US3732262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:45

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 04 NOV 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 14:52 (24 HR)                        |
| Collection date and time (derived)     | 04 NOV 2020 14:52                    |

US3732262

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

|                                                                                                                                                                                 |                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                                                                                                | 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 <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                                                                                                                                                     | 05 NOV 2020 18:00:22                                             |
| Patient Cloud Open Date & Time                                                                                                                                                  | 02 NOV 2020 00:01                                                |
| Patient Cloud Close Date & Time                                                                                                                                                 | 06 NOV 2020 23:59                                                |

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 02:45:52

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3732262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 00:01:46

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| TIMEPOINT                                                                                                                                                                       | DAY 103                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| TIMEPOINT                                                                                                                                                                       | DAY 194                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

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



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| TIMEPOINT                                                                                                                                                                       | DAY 397                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| TIMEPOINT                                                                                                                                                                       | DAY 439                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

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

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

**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 ☐ 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 ☐

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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18 JAN 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| TIMEPOINT                                                                                                                                                                       | DAY 509                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

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

**Form: Safety Follow Up Diary**

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

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

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21 JAN 2022 00:01

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25 JAN 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

**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 ☐



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**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 ☐

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01 FEB 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

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

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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08 FEB 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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15 FEB 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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18 FEB 2022 00:01

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22 FEB 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| TIMEPOINT                                                                                                                                                                       | DAY 544                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



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**Form: Safety Follow Up Diary**

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

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

Date and time of submission

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25 FEB 2022 00:01

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US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| TIMEPOINT                                                                                                                                                                       | DAY 551                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

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

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

Date and time of submission

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08 MAR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

**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 ☐

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15 MAR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

**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 ☐

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

**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 ☐



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

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29 MAR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

**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 ☐

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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05 APR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

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 ☐

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

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12 APR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

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 ☐

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

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19 APR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

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26 APR 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

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 ☐ 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 ☐

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| TIMEPOINT                                                                                                                                                                       | DAY 628                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

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 ☐

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| TIMEPOINT                                                                                                                                                                       | DAY 698                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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29 JUL 2022 00:01

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02 AUG 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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05 AUG 2022 00:01

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09 AUG 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| TIMEPOINT                                                                                                                                                                       | DAY 712                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



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12 AUG 2022 00:01

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16 AUG 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

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19 AUG 2022 00:01

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23 AUG 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

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26 AUG 2022 00:01

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30 AUG 2022 23:59

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Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

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06 SEP 2022 23:59

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Generated On: 26 Nov 2020 11:12:45

| TIMEPOINT                                                                                                                                                                       | DAY 740                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



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13 SEP 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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Date and time of submission

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20 SEP 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

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

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

Date and time of submission

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23 SEP 2022 00:01

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27 SEP 2022 23:59

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Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3732262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:12:45

| 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"/>                                               |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3732262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:45

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732262

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:12:45

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:12:45

|                                                  |                                                                  |
|--------------------------------------------------|------------------------------------------------------------------|
| Date of Contact                                  | 08 SEP 2020                                                      |
| Time of Contact                                  | 14:01                                                            |
| Date and Time of Contact (derived)               | 08 SEP 2020 14:01                                                |
| Type of Contact                                  | Clinic Visit - Scheduled <input type="checkbox"/>                |
|                                                  | Clinical Visit - Unscheduled <input checked="" type="checkbox"/> |
|                                                  | Safety Call <input type="checkbox"/>                             |
|                                                  | Convalescent Tele-visit <input type="checkbox"/>                 |
| Has the subject reported symptoms of SARS-COV-2? | Yes <input checked="" type="checkbox"/>                          |
|                                                  | No <input type="checkbox"/>                                      |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input checked="" type="checkbox"/> |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 11 SEP 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.8 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 317 of 2129 |                                  |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

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

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input type="checkbox"/>            |
|                         | Mild     | <input checked="" type="checkbox"/> |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |



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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input checked="" type="checkbox"/> |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

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Form: Symptom Log (3)

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|                      |                                       |                          |
|----------------------|---------------------------------------|--------------------------|
|                      | Day 34                                | <input type="checkbox"/> |
|                      | Day 35                                | <input type="checkbox"/> |
|                      | Day 36                                | <input type="checkbox"/> |
|                      | Day 37                                | <input type="checkbox"/> |
|                      | Day 38                                | <input type="checkbox"/> |
|                      | Day 39                                | <input type="checkbox"/> |
|                      | Day 40                                | <input type="checkbox"/> |
| Date                 | 12 SEP 2020                           |                          |
| Assessment Not Done  | False                                 |                          |
| O2 Saturation        | 99 %                                  |                          |
| O2 Saturation Units  | %                                     |                          |
| Temperature          | 98.8 F                                |                          |
| Chills               | None <input checked="" type="radio"/> |                          |
|                      | Mild <input type="radio"/>            |                          |
|                      | Moderate <input type="radio"/>        |                          |
|                      | Severe <input type="radio"/>          |                          |
|                      | Not Done <input type="radio"/>        |                          |
| Cough                | None <input checked="" type="radio"/> |                          |
|                      | Mild <input type="radio"/>            |                          |
|                      | Moderate <input type="radio"/>        |                          |
|                      | Severe <input type="radio"/>          |                          |
|                      | Not Done <input type="radio"/>        |                          |
| Shortness of Breath  | None <input checked="" type="radio"/> |                          |
|                      | Mild <input type="radio"/>            |                          |
|                      | Moderate <input type="radio"/>        |                          |
|                      | Severe <input type="radio"/>          |                          |
|                      | Not Done <input type="radio"/>        |                          |
| Difficulty Breathing | None <input checked="" type="radio"/> |                          |
|                      | Mild <input type="radio"/>            |                          |
|                      | Moderate <input type="radio"/>        |                          |
|                      | Severe <input type="radio"/>          |                          |
|                      | Not Done <input type="radio"/>        |                          |
| Fatigue              | None <input checked="" type="radio"/> |                          |
| v6.020 DTW (1102)    | 321 of 2129                           |                          |

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Form: Symptom Log (3)

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

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Form: Symptom Log (3)

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|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input type="checkbox"/>            |
|                         | Mild     | <input checked="" type="checkbox"/> |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Symptom Day](#)

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input checked="" type="checkbox"/> |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 13 SEP 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 99 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 99.0 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 325 of 2129 |                                  |

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

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

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input type="checkbox"/>            |
|                         | Mild     | <input checked="" type="checkbox"/> |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |



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Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input checked="" type="checkbox"/> |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

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Form: Symptom Log (5)

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|                      |                                       |                          |
|----------------------|---------------------------------------|--------------------------|
|                      | Day 34                                | <input type="checkbox"/> |
|                      | Day 35                                | <input type="checkbox"/> |
|                      | Day 36                                | <input type="checkbox"/> |
|                      | Day 37                                | <input type="checkbox"/> |
|                      | Day 38                                | <input type="checkbox"/> |
|                      | Day 39                                | <input type="checkbox"/> |
|                      | Day 40                                | <input type="checkbox"/> |
| Date                 | 14 SEP 2020                           |                          |
| Assessment Not Done  | False                                 |                          |
| O2 Saturation        | 99 %                                  |                          |
| O2 Saturation Units  | %                                     |                          |
| Temperature          | 99.1 F                                |                          |
| Chills               | None <input checked="" type="radio"/> |                          |
|                      | Mild <input type="radio"/>            |                          |
|                      | Moderate <input type="radio"/>        |                          |
|                      | Severe <input type="radio"/>          |                          |
|                      | Not Done <input type="radio"/>        |                          |
| Cough                | None <input checked="" type="radio"/> |                          |
|                      | Mild <input type="radio"/>            |                          |
|                      | Moderate <input type="radio"/>        |                          |
|                      | Severe <input type="radio"/>          |                          |
|                      | Not Done <input type="radio"/>        |                          |
| Shortness of Breath  | None <input checked="" type="radio"/> |                          |
|                      | Mild <input type="radio"/>            |                          |
|                      | Moderate <input type="radio"/>        |                          |
|                      | Severe <input type="radio"/>          |                          |
|                      | Not Done <input type="radio"/>        |                          |
| Difficulty Breathing | None <input checked="" type="radio"/> |                          |
|                      | Mild <input type="radio"/>            |                          |
|                      | Moderate <input type="radio"/>        |                          |
|                      | Severe <input type="radio"/>          |                          |
|                      | Not Done <input type="radio"/>        |                          |
| Fatigue              | None <input checked="" type="radio"/> |                          |
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Form: Symptom Log (5)

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

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
|                         | Severe   | <input type="checkbox"/>         |
|                         | Not Done | <input type="checkbox"/>         |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input checked="" type="checkbox"/> |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 15 SEP 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.6 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 333 of 2129 |                                  |

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

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

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Form: Symptom Log (6)

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|                         |          |                                  |
|-------------------------|----------|----------------------------------|
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |



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Form: Symptom Log (7)

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Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input checked="" type="checkbox"/> |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

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Form: Symptom Log (7)

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|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 16 SEP 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 99 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.6 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 337 of 2129 |                                  |

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Form: Symptom Log (7)

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

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Form: Symptom Log (7)

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|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input type="checkbox"/>            |
|                         | Mild     | <input checked="" type="checkbox"/> |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input checked="" type="checkbox"/> |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

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Form: Symptom Log (8)

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|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 17 SEP 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 100 %       |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.7 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 341 of 2129 |                                  |

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Form: Symptom Log (8)

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

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Form: Symptom Log (8)

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|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input type="checkbox"/>            |
|                         | Mild     | <input checked="" type="checkbox"/> |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |



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Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input checked="" type="checkbox"/> |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

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Form: Symptom Log (9)

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|                      |                                       |                          |
|----------------------|---------------------------------------|--------------------------|
|                      | Day 34                                | <input type="checkbox"/> |
|                      | Day 35                                | <input type="checkbox"/> |
|                      | Day 36                                | <input type="checkbox"/> |
|                      | Day 37                                | <input type="checkbox"/> |
|                      | Day 38                                | <input type="checkbox"/> |
|                      | Day 39                                | <input type="checkbox"/> |
|                      | Day 40                                | <input type="checkbox"/> |
| Date                 | 18 SEP 2020                           |                          |
| Assessment Not Done  | False                                 |                          |
| O2 Saturation        | 100 %                                 |                          |
| O2 Saturation Units  | %                                     |                          |
| Temperature          | 99.7 F                                |                          |
| Chills               | None <input checked="" type="radio"/> |                          |
|                      | Mild <input type="radio"/>            |                          |
|                      | Moderate <input type="radio"/>        |                          |
|                      | Severe <input type="radio"/>          |                          |
|                      | Not Done <input type="radio"/>        |                          |
| Cough                | None <input checked="" type="radio"/> |                          |
|                      | Mild <input type="radio"/>            |                          |
|                      | Moderate <input type="radio"/>        |                          |
|                      | Severe <input type="radio"/>          |                          |
|                      | Not Done <input type="radio"/>        |                          |
| Shortness of Breath  | None <input checked="" type="radio"/> |                          |
|                      | Mild <input type="radio"/>            |                          |
|                      | Moderate <input type="radio"/>        |                          |
|                      | Severe <input type="radio"/>          |                          |
|                      | Not Done <input type="radio"/>        |                          |
| Difficulty Breathing | None <input checked="" type="radio"/> |                          |
|                      | Mild <input type="radio"/>            |                          |
|                      | Moderate <input type="radio"/>        |                          |
|                      | Severe <input type="radio"/>          |                          |
|                      | Not Done <input type="radio"/>        |                          |
| Fatigue              | None <input checked="" type="radio"/> |                          |
| v6.020 DTW (1102)    | 345 of 2129                           |                          |

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Form: Symptom Log (9)

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

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
|                         | Severe   | <input type="checkbox"/>         |
|                         | Not Done | <input type="checkbox"/>         |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input checked="" type="checkbox"/> |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 19 SEP 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 99 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.4 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 349 of 2129 |                                  |

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

|  |          |                          |
|--|----------|--------------------------|
|  | Mild     | <input type="checkbox"/> |
|  | Moderate | <input type="checkbox"/> |
|  | Severe   | <input type="checkbox"/> |
|  | Not Done | <input type="checkbox"/> |

|                        |          |                                     |
|------------------------|----------|-------------------------------------|
| Muscle Aches (Myalgia) | None     | <input checked="" type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/>            |
|                        | Moderate | <input type="checkbox"/>            |
|                        | Severe   | <input type="checkbox"/>            |
|                        | Not Done | <input type="checkbox"/>            |

|            |          |                                     |
|------------|----------|-------------------------------------|
| Body Aches | None     | <input checked="" type="checkbox"/> |
|            | Mild     | <input type="checkbox"/>            |
|            | Moderate | <input type="checkbox"/>            |
|            | Severe   | <input type="checkbox"/>            |
|            | Not Done | <input type="checkbox"/>            |

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

|                   |          |                                     |
|-------------------|----------|-------------------------------------|
| New Loss of Taste | None     | <input checked="" type="checkbox"/> |
|                   | Mild     | <input type="checkbox"/>            |
|                   | Moderate | <input type="checkbox"/>            |
|                   | Severe   | <input type="checkbox"/>            |
|                   | Not Done | <input type="checkbox"/>            |

|                   |          |                                     |
|-------------------|----------|-------------------------------------|
| New Loss of Smell | None     | <input checked="" type="checkbox"/> |
|                   | Mild     | <input type="checkbox"/>            |
|                   | Moderate | <input type="checkbox"/>            |
|                   | Severe   | <input type="checkbox"/>            |
|                   | Not Done | <input type="checkbox"/>            |

|                  |          |                                     |
|------------------|----------|-------------------------------------|
| Nasal Congestion | None     | <input checked="" type="checkbox"/> |
|                  | Mild     | <input type="checkbox"/>            |
|                  | Moderate | <input type="checkbox"/>            |

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |



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Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input checked="" type="checkbox"/> |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 21 SEP 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 99 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.5 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 353 of 2129 |                                  |

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

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

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input checked="" type="checkbox"/> |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 22 SEP 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 99 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.2 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 357 of 2129 |                                  |

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

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

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |



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Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input checked="" type="checkbox"/> |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 23 SEP 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 99 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.7 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 361 of 2129 |                                  |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

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

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

|                         |          |                                     |
|-------------------------|----------|-------------------------------------|
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Nausea                  | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Vomiting                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Diarrhea                | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |
| Sore Throat             | None     | <input checked="" type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/>            |
|                         | Moderate | <input type="checkbox"/>            |
|                         | Severe   | <input type="checkbox"/>            |
|                         | Not Done | <input type="checkbox"/>            |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input checked="" type="checkbox"/> |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 30 SEP 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 99 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 99.1 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 365 of 2129 |                                  |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

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

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input checked="" type="checkbox"/> |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |
| Day 33 | <input type="checkbox"/>            |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

|                      |                                       |                          |
|----------------------|---------------------------------------|--------------------------|
|                      | Day 34                                | <input type="checkbox"/> |
|                      | Day 35                                | <input type="checkbox"/> |
|                      | Day 36                                | <input type="checkbox"/> |
|                      | Day 37                                | <input type="checkbox"/> |
|                      | Day 38                                | <input type="checkbox"/> |
|                      | Day 39                                | <input type="checkbox"/> |
|                      | Day 40                                | <input type="checkbox"/> |
| Date                 | 10 SEP 2020                           |                          |
| Assessment Not Done  | False                                 |                          |
| O2 Saturation        | 98 %                                  |                          |
| O2 Saturation Units  | %                                     |                          |
| Temperature          | 100.0 F                               |                          |
| Chills               | None <input checked="" type="radio"/> |                          |
|                      | Mild <input type="radio"/>            |                          |
|                      | Moderate <input type="radio"/>        |                          |
|                      | Severe <input type="radio"/>          |                          |
|                      | Not Done <input type="radio"/>        |                          |
| Cough                | None <input checked="" type="radio"/> |                          |
|                      | Mild <input type="radio"/>            |                          |
|                      | Moderate <input type="radio"/>        |                          |
|                      | Severe <input type="radio"/>          |                          |
|                      | Not Done <input type="radio"/>        |                          |
| Shortness of Breath  | None <input checked="" type="radio"/> |                          |
|                      | Mild <input type="radio"/>            |                          |
|                      | Moderate <input type="radio"/>        |                          |
|                      | Severe <input type="radio"/>          |                          |
|                      | Not Done <input type="radio"/>        |                          |
| Difficulty Breathing | None <input checked="" type="radio"/> |                          |
|                      | Mild <input type="radio"/>            |                          |
|                      | Moderate <input type="radio"/>        |                          |
|                      | Severe <input type="radio"/>          |                          |
|                      | Not Done <input type="radio"/>        |                          |
| Fatigue              | None <input checked="" type="radio"/> |                          |
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Form: Symptom Log (15)

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

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:12:45

|                                                                               |                                                                                                                                                              |
|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Visit                                                                 | 10 SEP 2020                                                                                                                                                  |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                             |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR?                           | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                             |
| Date of Test                                                                  | 10 SEP 2020                                                                                                                                                  |
| Type of Test Performed                                                        | Nasopharyngeal Swab <input checked="" type="radio"/><br>Nasal Swab <input type="radio"/><br>Saliva Test <input type="radio"/><br>Other <input type="radio"/> |
| Other, specify _____                                                          |                                                                                                                                                              |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                             |
| If yes, provide lab information below                                         |                                                                                                                                                              |
| Lab/ Institution Test Performed                                               | _____                                                                                                                                                        |
| CLIA Certified?                                                               | Yes <input type="radio"/><br>No <input type="radio"/>                                                                                                        |
| COVID-19 Positive (CSA Programming Field Only)                                | 1                                                                                                                                                            |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:45

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

If Yes, provide:

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

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

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

If Yes, provide:

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

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

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

If Yes, provide:

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

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

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

If Yes, provide:

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

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

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

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

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

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

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:45

**Ventilator Support:**

High-Flow Oxygen? Yes ☐  
No ☒

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

End Date \_\_\_\_\_

Non-Invasive Ventilation? Yes ☐  
No ☐

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

End Date \_\_\_\_\_

Mechanical Ventilation? Yes ☐  
No ☐

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

End Date \_\_\_\_\_

ECMO? Yes ☐  
No ☐

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

End Date \_\_\_\_\_

**Evidence of Shock:**

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

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

End Date \_\_\_\_\_

Evidence of Shock Requires Vasopressors Yes ☐  
No ☐

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

End Date \_\_\_\_\_

Acute Renal Dysfunction? Yes ☐  
No ☐

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

Hepatic Dysfunction? Yes ☐  
No ☐

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

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:45

Neurologic Dysfunction? Yes ☐  
No ☐

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐  
No ☒

Date of Assessment

Radiographical Evidence Yes ☐  
No ☐

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐  
No ☒

Start Date

End Date



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:12:45

[Generate Next COVID-19 Assessment](#)

Yes ☐  
No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:12:45

| Visit  | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3  | Yes                   | 12 SEP 2020        |
| Day 5  | Yes                   | 14 SEP 2020        |
| Day 7  | Yes                   | 16 SEP 2020        |
| Day 9  | Yes                   | 18 SEP 2020        |
| Day 14 | Yes                   | 23 SEP 2020        |
| Day 21 | Yes                   | 30 SEP 2020        |
| Day 28 | Yes                   | 07 OCT 2020        |

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:45

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 10 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                                                      | SICKD1                                  |

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

|                                           |                                       |
|-------------------------------------------|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|                                           | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 10 SEP 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 12:15 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 10 SEP 2020 12:15                     |
| Height ( <i>xxx.x</i> )                   | 161.6 cm                              |
| Weight ( <i>xxx.x</i> )                   | 81.0 kg                               |
| Temperature ( <i>xxx.x</i> )              | 100.0 F                               |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|                                           | Axillary <input type="radio"/>        |
|                                           | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 73 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 16 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 143 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 89 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3732262

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3732262

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:12:45

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 SEP 2020

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:45

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 07 OCT 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | SICKD28                                 |

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

|                                           |                                       |
|-------------------------------------------|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|                                           | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 07 OCT 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 14:05 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 07 OCT 2020 14:05                     |
| Height ( <i>xxx.x</i> )                   | 162.3 cm                              |
| Weight ( <i>xxx.x</i> )                   | 080.3 kg                              |
| Temperature ( <i>xxx.x</i> )              | 98.6 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|                                           | Axillary <input type="radio"/>        |
|                                           | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 92 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 14 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 119 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 70 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |



US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 2020

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

US3732262

**Folder: Convalescence Visit Day 28 (1)**

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

**Generated On: 26 Nov 2020 11:12:45**

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

07 OCT 2020

US3732262

Folder: Unscheduled 10 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 11:12:45

Visit Date

Please check all assessments that apply for this visit

|                           |       |
|---------------------------|-------|
| Physical Exam             | False |
| Vital Signs               | False |
| Immunogenicity Assessment | False |
| Pregnancy Test            | False |

US3732262

Folder: Unscheduled 10 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

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

US3732262

Folder: Unscheduled 10 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:45

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.*

US3732262

Folder: Unscheduled 10 Sep 2020

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:12:45

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) \_\_\_\_\_

US3732262

Folder: Unscheduled 10 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:45

Was the sample collected?

Yes ☐

No ☐

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3732262

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:12:45

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:45

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US102-2020-MRNA-1273-P30<br>1000001                                                                                                                          |
| Adverse event                                                  | SYMPTOMATIC COVID-19                                                                                                                                             |
| Was this a medically-attended AE?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 06 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)                         | 19 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)                                              | 392 of 2129                                                                                                                                                      |

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:45

|                                                                                       |                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Persistent or significant disability or incapacity                                    | False                                                                                                                                                                                                                                                                           |
| Congenital anomaly or birth defect                                                    | False                                                                                                                                                                                                                                                                           |
| Other medically important event                                                       | False                                                                                                                                                                                                                                                                           |
| Relationship to investigational product                                               | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Relationship to Study Procedure                                                       | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Action taken with investigational product                                             | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product <input checked="" 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)                            | 1                                                                                                                                                                                                                                                                               |
| Admitted to ICU Derived (CSA Programming Field Only)                                  | _____                                                                                                                                                                                                                                                                           |

US3732262

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

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

**Generated On: 26 Nov 2020 11:12:45**

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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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US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:45

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | LOSARTAN                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HYPERTENSION                                                                                                                                                                                                                                                                                                                                                                                                             |
| Dose per administration        | 50                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input 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"/>                                                                                                                                                                                            |

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:12:45

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

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:45

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | IBUPROFEN                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | MIGRAINE HEADACHES                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose per administration        | 800                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:12:45

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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 2017                         |
| 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"/>            |

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:45

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | TYLENOL                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | E-DIARY PAIN - HEADACHE                                                                                                                                                                                                                                                                                                                                                                                                  |
| Dose per administration        | 500                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |



US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:12:45

|                                                                   |                          |                                     |
|-------------------------------------------------------------------|--------------------------|-------------------------------------|
|                                                                   | 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)                                          |                          | 04 SEP 2020                         |
| Start date completely unknown                                     |                          | False                               |
| Ongoing?                                                          | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            |                          | 04 SEP 2020                         |
| <hr/>                                                             |                          |                                     |
| Was this medication taken for solicited event?                    | Yes                      | <input checked="" type="checkbox"/> |
|                                                                   | No                       | <input type="checkbox"/>            |
| <hr/>                                                             |                          |                                     |
| Separate Dosage Number (derived)                                  |                          | <input type="text"/>                |
| Interval Dosage Unit Number (derived)                             |                          | <input type="text"/>                |
| Interval Dosage Definition (derived)                              |                          | 802 <input type="checkbox"/>        |
|                                                                   |                          | 803 <input type="checkbox"/>        |
|                                                                   |                          | 804 <input type="checkbox"/>        |

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:45

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | TYLENOL                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | SYMPTOMATIC COVID-19                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose per administration        | 500                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:12:45

|                                                                   |                          |                                     |
|-------------------------------------------------------------------|--------------------------|-------------------------------------|
|                                                                   | 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)                                          |                          | 12 SEP 2020                         |
| Start date completely unknown                                     |                          | False                               |
| Ongoing?                                                          | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            |                          | 19 SEP 2020                         |
| Was this medication taken for solicited event?                    | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| Separate Dosage Number (derived)                                  |                          | <input type="text"/>                |
| Interval Dosage Unit Number (derived)                             |                          | <input type="text"/>                |
| Interval Dosage Definition (derived)                              | 802                      | <input type="checkbox"/>            |
|                                                                   | 803                      | <input type="checkbox"/>            |
|                                                                   | 804                      | <input type="checkbox"/>            |

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:45

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | TYLENOL                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | MENSTRUAL CRAMPS                                                                                                                                                                                                                                                                                                                                                                                                         |
| Dose per administration        | 500                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:12:45

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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 2014                         |
| 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"/>            |

US3732262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:45

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | IBUPROFEN                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | LEFT SPRAINED ANKLE                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose per administration        | 800                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:12:45

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:45

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:12:45

|                                                                   |                          |                                     |
|-------------------------------------------------------------------|--------------------------|-------------------------------------|
|                                                                   | 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)                                          |                          | 16 OCT 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)                            |                          | 16 OCT 2020                         |
| Was this medication taken for solicited event?                    | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| Separate Dosage Number (derived)                                  |                          | <input type="text"/>                |
| Interval Dosage Unit Number (derived)                             |                          | <input type="text"/>                |
| Interval Dosage Definition (derived)                              | 802                      | <input type="checkbox"/>            |
|                                                                   | 803                      | <input type="checkbox"/>            |
|                                                                   | 804                      | <input type="checkbox"/>            |

US3732262

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 11:12:45**

---

Were any concomitant procedures performed?

Yes ☐

No ☐

---

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

---

US3732262

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:12:45

|       |                 |                          |
|-------|-----------------|--------------------------|
| Visit | Screening       | <input type="checkbox"/> |
|       | Visit 1 Day 1   | <input type="checkbox"/> |
|       | Visit 2 Day 29  | <input type="checkbox"/> |
|       | Visit 3 Day 57  | <input type="checkbox"/> |
|       | Visit 4 Day 209 | <input type="checkbox"/> |
|       | Visit 5 Day 394 | <input type="checkbox"/> |
|       | Visit 6 Day 759 | <input type="checkbox"/> |

**Case Report Form**

|                                                                            |  |
|----------------------------------------------------------------------------|--|
| Visit Date                                                                 |  |
| Demographics                                                               |  |
| Enrollment                                                                 |  |
| Inclusion/Exclusion Criteria Summary                                       |  |
| Inclusion/Exclusion Criteria                                               |  |
| Medical History Summary                                                    |  |
| Medical History                                                            |  |
| Vital Signs                                                                |  |
| Vital Signs - Dosing                                                       |  |
| Physical Examination                                                       |  |
| Central Laboratory - Nasopharyngeal Swab                                   |  |
| Childbearing Potential                                                     |  |
| Pregnancy Test                                                             |  |
| Randomization                                                              |  |
| Exposure                                                                   |  |
| Immunogenicity Assessment                                                  |  |
| Saliva Collection                                                          |  |
| COVID Diagnostic Test                                                      |  |
| Symptom Log                                                                |  |
| Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection |  |
| COVID-19 Severity Assessment                                               |  |
| COVID-19 Contact                                                           |  |
| Risk of Exposure                                                           |  |
| Safety Call                                                                |  |
| Dosing Discontinuation                                                     |  |
| End of Study / Study Discontinuation                                       |  |

US3732262

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:12:45

|                                                     |  |
|-----------------------------------------------------|--|
| All                                                 |  |
| Date of missed or out of window visit or assessment |  |
| <b>Category</b>                                     |  |
| Inclusion criteria not met/Exclusion criteria met   |  |
| Study Treatment not given                           |  |
| Missed Visit                                        |  |
| Missed Assessment                                   |  |
| Visit performed out of window                       |  |
| Assessment performed out of window                  |  |
| Scheduled clinical visit performed as home visit    |  |
| Other                                               |  |
| Other, specify                                      |  |
| <b>Description of Relationship to COVID-19</b>      |  |
| Clinical site closed                                |  |
| Travel restrictions                                 |  |
| Quarantine due to COVID-19                          |  |
| Possible exposure to COVID-19                       |  |
| Exposure to COVID-19                                |  |
| Presumption / confirmed COVID-19                    |  |
| Symptoms of COVID-19                                |  |
| Sponsor hold due to COVID-19                        |  |
| Participant decision                                |  |

US3732262

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:12:45

Date of dosing discontinuation (dd MMM yyyy)

06 SEP 2020

Primary reason for dosing discontinuation

AE (specify) ☒

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

SYMPTOMATIC COVID-19

US3732262

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:12:45

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 ☐

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

|                                                                |                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                          | USA-US102-2020-MRNA-1273-P301000001                              |
| Serious                                                        | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Death                                                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                      | SCOTT                                                            |
| Investigator's Last Name                                       | OVERCASH                                                         |
| Site Address: Street                                           | 5565 GROSSMONT CENTER DR                                         |
| Site Address: City                                             | LA MESA                                                          |
| Site Address: State                                            | CA                                                               |
| Site Address: Postal Code                                      | 91942                                                            |
| Investigator Country                                           | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                             | 5                                                                |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:12:45

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US102-2020-MRNA-1273-P301000001                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | SCOTT                                                            |
| Investigator's Last Name                                                                                                                                                                      | OVERCASH                                                         |
| Site Address: Street                                                                                                                                                                          | 5565 GROSSMONT CENTER DR                                         |
| Site Address: City                                                                                                                                                                            | LA MESA                                                          |
| Site Address: State                                                                                                                                                                           | CA                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 91942                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 10/SEP/2020 12:43                                                |
| 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                                                             |



US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:12:45

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US102-2020-MRNA-1273-P301000001                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | SCOTT                                                            |
| Investigator's Last Name                                                                                                                                                                      | OVERCASH                                                         |
| Site Address: Street                                                                                                                                                                          | 5565 GROSSMONT CENTER DR                                         |
| Site Address: City                                                                                                                                                                            | LA MESA                                                          |
| Site Address: State                                                                                                                                                                           | CA                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 91942                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 23/SEP/2020 13:55                                                |
| 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                                                             |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:12:45

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US102-2020-MRNA-1273-P301000001                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | SCOTT                                                            |
| Investigator's Last Name                                                                                                                                                                      | OVERCASH                                                         |
| Site Address: Street                                                                                                                                                                          | 5565 GROSSMONT CENTER DR                                         |
| Site Address: City                                                                                                                                                                            | LA MESA                                                          |
| Site Address: State                                                                                                                                                                           | CA                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 91942                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 08/OCT/2020 13:57                                                |
| 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                                                             |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:12:45

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US102-2020-MRNA-1273-P301000001                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | SCOTT                                                            |
| Investigator's Last Name                                                                                                                                                                      | OVERCASH                                                         |
| Site Address: Street                                                                                                                                                                          | 5565 GROSSMONT CENTER DR                                         |
| Site Address: City                                                                                                                                                                            | LA MESA                                                          |
| Site Address: State                                                                                                                                                                           | CA                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 91942                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 15/OCT/2020 10:15                                                |
| 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                                                             |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:12:45

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US102-2020-MRNA-1273-P301000001                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | SCOTT                                                            |
| Investigator's Last Name                                                                                                                                                                      | OVERCASH                                                         |
| Site Address: Street                                                                                                                                                                          | 5565 GROSSMONT CENTER DR                                         |
| Site Address: City                                                                                                                                                                            | LA MESA                                                          |
| Site Address: State                                                                                                                                                                           | CA                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 91942                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 06/NOV/2020 19:14                                                |
| 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

US3732262 (Prod: eStudySite - La Mesa - PPDS)

US3732262

**Form: Participant Creation**

**Generated On: 26 Nov 2020 11:12:45**

[Participant ID](#)

| Audit                    | User                             | Time (GMT)           |
|--------------------------|----------------------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6)                 | 23 Oct 2020 22:40:12 |
| User entered 'US3732262' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 22:09:22 |

US3732262

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

[Was this visit performed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:40:31 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:22:57 |

US3732262

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:40:31 |
| User entered '02 SEP 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 22:09:23 |



US3732262

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                 | 23 Oct 2020 22:40:31 |
| User entered 'Clinic (Clinic)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:22:57 |

US3732262

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

[Folder OID](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 04 Sep 2020 18:22:57 |

US3732262

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:45

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:43:47 |
| User entered (b) (6) 1983' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 22:09:24 |

US3732262

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:45

[Age](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:43:47 |
| User entered '37'   | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:23 |

US3732262

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:12:45**

[Age Units](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 04 Sep 2020 18:23:23 |

US3732262

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:12:45**

[Age \(Derived\)](#)

| Audit             | User   | Time (GMT)           |
|-------------------|--------|----------------------|
| User entered '37' | System | 02 Sep 2020 23:18:46 |

US3732262

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:45

[Sex](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                 | 23 Oct 2020 22:43:47 |
| User entered 'Female (F)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:23 |

US3732262

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:12:45**

[Ethnicity](#)

| Audit                                                  | User                             | Time (GMT)           |
|--------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)                 | 23 Oct 2020 22:43:47 |
| User entered 'Hispanic or Latino (HISPANIC OR LATINO)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:23 |



US3732262

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:45

[White](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:43:47 |
| User entered '1'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:23 |

US3732262

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:45

[Black](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:43:47 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:23 |

US3732262

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:12:45**

[Asian](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:43:47 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:23 |

US3732262

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:12:45**

[American Indian or Alaska Native](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:43:47 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:23 |

US3732262

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:12:45**

[Native Hawaiian or other Pacific Islander](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:43:47 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:23 |

US3732262

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:12:45**

[Other](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:43:47 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:23 |

US3732262

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:12:45**

[If race is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:43:47 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:23 |

US3732262

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:12:45

[Unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:43:47 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:23 |



US3732262

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:12:45**

[Not reported](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:43:47 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:23 |

US3732262

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:12:45**

[Date of Informed Consent \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:46:55 |
| User entered '02 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 02 Sep 2020 23:18:46 |

US3732262

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Sep 2020' | System | 02 Sep 2020 23:18:46 |

US3732262

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 02 Sep 2020 23:18:46 |

US3732262

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:12:45**

[Protocol Version](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                 | 23 Oct 2020 22:46:55 |
| User entered 'Amendment 3 (3)' | Lauren Arnett (b) (4)<br>(b) (4) | 02 Sep 2020 23:18:46 |

US3732262

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:46:55 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 02 Sep 2020 23:18:46 |

US3732262

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:46:55 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 02 Sep 2020 23:18:46 |

US3732262

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:12:45**

If reason for screen fail is Other, specify

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:46:55 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 02 Sep 2020 23:18:46 |



US3732262

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:12:45**

[Was this participant screened previously?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:46:55 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 02 Sep 2020 23:18:46 |

US3732262

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:12:45**

[If Yes, previous participant number](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:46:55 |
| User entered empty. | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 22:09:23 |

US3732262

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:12:45**

[Enrollment Trigger](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Sep 2020 23:18:51 |

US3732262

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:47:03 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 02 Sep 2020 23:18:51 |

US3732262

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 11:12:45**

[Were any significant conditions reported?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:47:10 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:28 |

US3732262

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:12:45

[Condition](#)

| Audit                                                                                                                                                                                   | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                     | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0. | Coder Import (b) (4)  | 04 Sep 2020 18:25:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                             | (b) (4)               | 04 Sep 2020 18:25:41 |
| Data point term sent to Coder                                                                                                                                                           | System                | 04 Sep 2020 18:24:26 |
| User entered 'environmental allergies'                                                                                                                                                  | Lauren Arnett (b) (4) | 04 Sep 2020 18:23:47 |
|                                                                                                                                                                                         | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 1996' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:47 |

US3732262

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:47 |



US3732262

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition ongoing at study entry](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:47 |

US3732262

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:47 |

US3732262

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Stop date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:23:47 |

US3732262

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1996' | System | 04 Sep 2020 18:23:47 |

US3732262

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1996' | System | 04 Sep 2020 18:23:47 |

US3732262

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:23:47 |

US3732262

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:23:47 |

US3732262

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:12:45

[Condition](#)

| Audit                                                                                                                                                                                   | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                     | (b) (4), (b) (6)         | 23 Oct 2020 22:50:18 |
| User coded data point as SOC: Eye disorders, HLGT: Coder Import<br>Vision disorders, HLT: Refractive and<br>accommodative disorders, PT: Myopia, LLT: Myopia<br>- version MedDRA\\23.0. | (b) (4)                  | 04 Sep 2020 18:25:43 |
| User coded data point as Term Coded data point by<br>User: Coder System - version MedDRA\\23.0.                                                                                         | Coder Import<br>(b) (4)  | 04 Sep 2020 18:25:43 |
| Data point term sent to Coder                                                                                                                                                           | System                   | 04 Sep 2020 18:24:27 |
| User entered 'myopia'                                                                                                                                                                   | Lauren Arnett<br>(b) (4) | 04 Sep 2020 18:24:01 |



US3732262

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 1996' | Lauren Arnett (b) (4) | 04 Sep 2020 18:24:01 |
|                            | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:01 |

US3732262

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition ongoing at study entry](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:01 |

US3732262

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 2010' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:01 |

US3732262

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Stop date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:01 |

US3732262

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1996' | System | 04 Sep 2020 18:24:01 |

US3732262

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1996' | System | 04 Sep 2020 18:24:01 |

US3732262

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 04 Sep 2020 18:24:01 |



US3732262

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2010' | System | 04 Sep 2020 18:24:01 |

US3732262

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:12:45

[Condition](#)

| Audit                                                                                                                                                                       | User                             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                         | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Astigmatism - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 04 Sep 2020 18:25:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                | Coder Import (b) (4)<br>(b) (4)  | 04 Sep 2020 18:25:43 |
| Data point term sent to Coder                                                                                                                                               | System                           | 04 Sep 2020 18:24:26 |
| User entered 'astigmatism'                                                                                                                                                  | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:17 |

US3732262

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 1996' | Lauren Arnett (b) (4) | 04 Sep 2020 18:24:17 |
|                            | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:17 |

US3732262

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition ongoing at study entry](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User entered 'No (N)' | Lauren Arnett (b) (4) | 04 Sep 2020 18:24:17 |
|                       | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 2010' | Lauren Arnett (b) (4) | 04 Sep 2020 18:24:17 |
|                            | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Stop date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:17 |

US3732262

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1996' | System | 04 Sep 2020 18:24:17 |



US3732262

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1996' | System | 04 Sep 2020 18:24:17 |

US3732262

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 04 Sep 2020 18:24:17 |

US3732262

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2010' | System | 04 Sep 2020 18:24:17 |

US3732262

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:12:45

[Condition](#)

| Audit                                                                                                                                                                   | User                  | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                     | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Rosaceas, PT: Rosacea, LLT: Rosacea - version MedDRA\\23.0. | Coder Import (b) (4)  | 05 Sep 2020 09:15:54 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                 | Coder Import (b) (4)  | 05 Sep 2020 09:15:54 |
| Data point term sent to Coder                                                                                                                                           | System                | 04 Sep 2020 18:25:30 |
| User entered 'rosacea - facial'                                                                                                                                         | Lauren Arnett (b) (4) | 04 Sep 2020 18:24:33 |
|                                                                                                                                                                         | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 2013' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:33 |

US3732262

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:33 |

US3732262

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition ongoing at study entry](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:33 |

US3732262

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:33 |



US3732262

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Stop date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:33 |

US3732262

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2013' | System | 04 Sep 2020 18:24:33 |

US3732262

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2013' | System | 04 Sep 2020 18:24:33 |

US3732262

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:24:33 |

US3732262

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:24:33 |

US3732262

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:12:45

[Condition](#)

| Audit                                                                                                                                                                                                                                          | User                  | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                            | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0. | Coder Import (b) (4)  | 04 Sep 2020 18:26:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                                   | Coder Import (b) (4)  | 04 Sep 2020 18:26:46 |
| Data point term sent to Coder                                                                                                                                                                                                                  | System                | 04 Sep 2020 18:25:28 |
| User entered 'constipation'                                                                                                                                                                                                                    | Lauren Arnett (b) (4) | 04 Sep 2020 18:24:44 |
|                                                                                                                                                                                                                                                | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 1989' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:44 |

US3732262

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:44 |



US3732262

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition ongoing at study entry](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:44 |

US3732262

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:44 |

US3732262

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Stop date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:24:44 |

US3732262

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1989' | System | 04 Sep 2020 18:24:44 |

US3732262

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1989' | System | 04 Sep 2020 18:24:44 |

US3732262

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:24:44 |

US3732262

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:24:44 |

US3732262

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:12:45

[Condition](#)

| Audit                                                                                                                                                                                                                | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                  | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0. | Coder Import (b) (4)  | 04 Sep 2020 18:26:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                         | Coder Import (b) (4)  | 04 Sep 2020 18:26:46 |
| Data point term sent to Coder                                                                                                                                                                                        | System                | 04 Sep 2020 18:25:30 |
| User entered 'uncomplicated urinary tract infection'                                                                                                                                                                 | Lauren Arnett (b) (4) | 04 Sep 2020 18:25:04 |



US3732262

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 2014' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:25:04 |

US3732262

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:25:04 |

US3732262

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition ongoing at study entry](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:25:04 |

US3732262

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 2014' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:25:04 |

US3732262

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Stop date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:25:04 |

US3732262

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 04 Sep 2020 18:25:04 |

US3732262

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2014' | System | 04 Sep 2020 18:25:04 |

US3732262

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 04 Sep 2020 18:25:04 |



US3732262

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2014' | System | 04 Sep 2020 18:25:04 |

US3732262

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition](#)

| Audit                                                                                                                                                                                                                               | User                             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                 | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anemia - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 04 Sep 2020 18:26:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                        | Coder Import (b) (4)<br>(b) (4)  | 04 Sep 2020 18:26:46 |
| Data point term sent to Coder                                                                                                                                                                                                       | System                           | 04 Sep 2020 18:25:30 |
| User entered 'iron deficiency anemia'                                                                                                                                                                                               | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:25:23 |

US3732262

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 1998' | Lauren Arnett (b) (4) | 04 Sep 2020 18:25:23 |
|                            | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:25:23 |

US3732262

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition ongoing at study entry](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:25:23 |

US3732262

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 1999' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:25:23 |

US3732262

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Stop date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:25:23 |

US3732262

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1998' | System | 04 Sep 2020 18:25:23 |



US3732262

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1998' | System | 04 Sep 2020 18:25:23 |

US3732262

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1999' | System | 04 Sep 2020 18:25:23 |

US3732262

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1999' | System | 04 Sep 2020 18:25:23 |

US3732262

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:12:45

[Condition](#)

| Audit                                                                                                                                                          | User                             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                            | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 04 Sep 2020 18:27:47 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                   | Coder Import (b) (4)<br>(b) (4)  | 04 Sep 2020 18:27:47 |
| Data point term sent to Coder                                                                                                                                  | System                           | 04 Sep 2020 18:26:32 |
| User entered 'migraine headaches'                                                                                                                              | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:25:34 |

US3732262

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 2017' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:25:34 |

US3732262

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:25:34 |

US3732262

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition ongoing at study entry](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:25:34 |

US3732262

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:25:34 |



US3732262

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:12:45**

[Stop date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:25:34 |

US3732262

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2017' | System | 04 Sep 2020 18:25:34 |

US3732262

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2017' | System | 04 Sep 2020 18:25:34 |

US3732262

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:25:34 |

US3732262

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:25:34 |

US3732262

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:12:45

[Condition](#)

| Audit                                                                                                                                                                                                         | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                           | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Perinatal depression, LLT: Postpartum depression - version MedDRA\\23.0. | Coder Import (b) (4)  | 04 Sep 2020 18:28:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                  | (b) (4)               | 04 Sep 2020 18:28:39 |
| Data point term sent to Coder                                                                                                                                                                                 | System                | 04 Sep 2020 18:27:43 |
| User entered 'post-partum depression'                                                                                                                                                                         | Lauren Arnett (b) (4) | 04 Sep 2020 18:26:37 |
|                                                                                                                                                                                                               | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 2014' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:26:37 |

US3732262

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:26:37 |



US3732262

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition ongoing at study entry](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User entered 'No (N)' | Lauren Arnett (b) (4) | 04 Sep 2020 18:26:37 |
|                       | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 2014' | Lauren Arnett (b) (4) | 04 Sep 2020 18:26:37 |
|                            | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:12:45**

[Stop date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:26:37 |

US3732262

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 04 Sep 2020 18:26:37 |

US3732262

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2014' | System | 04 Sep 2020 18:26:37 |

US3732262

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 04 Sep 2020 18:26:37 |

US3732262

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2014' | System | 04 Sep 2020 18:26:37 |

US3732262

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:12:45

[Condition](#)

| Audit                                                                                                                                                               | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                 | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0. | Coder Import (b) (4)  | 04 Sep 2020 18:28:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                        | (b) (4)               | 04 Sep 2020 18:28:39 |
| Data point term sent to Coder                                                                                                                                       | System                | 04 Sep 2020 18:27:43 |
| User entered 'anxiety'                                                                                                                                              | Lauren Arnett (b) (4) | 04 Sep 2020 18:26:56 |
|                                                                                                                                                                     | (b) (4)               |                      |



US3732262

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 2014' | Lauren Arnett (b) (4) | 04 Sep 2020 18:26:56 |
|                            | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:26:56 |

US3732262

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition ongoing at study entry](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:26:56 |

US3732262

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:26:56 |

US3732262

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:12:45**

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4) | 04 Sep 2020 18:26:56 |
|                     | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 04 Sep 2020 18:26:56 |

US3732262

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2014' | System | 04 Sep 2020 18:26:56 |

US3732262

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:26:56 |



US3732262

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:26:56 |

US3732262

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition](#)

| Audit                                                                                                                                                                                                                     | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                       | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Papilloma viral infections, PT: Papilloma viral infection, LLT: Human papilloma virus infection - version MedDRA\\23.0. | Coder Import (b) (4)  | 04 Sep 2020 18:28:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                              | Coder Import (b) (4)  | 04 Sep 2020 18:28:39 |
| Data point term sent to Coder                                                                                                                                                                                             | System                | 04 Sep 2020 18:27:44 |
| User entered 'human papillomavirus'                                                                                                                                                                                       | Lauren Arnett (b) (4) | 04 Sep 2020 18:27:25 |
|                                                                                                                                                                                                                           | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 2019' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:27:25 |

US3732262

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:27:25 |

US3732262

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition ongoing at study entry](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:27:25 |

US3732262

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:27:25 |

US3732262

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 11:12:45**

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4) | 04 Sep 2020 18:27:25 |
|                     | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2019' | System | 04 Sep 2020 18:27:25 |



US3732262

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2019' | System | 04 Sep 2020 18:27:25 |

US3732262

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:27:25 |

US3732262

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:27:25 |

US3732262

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:12:45

[Condition](#)

| Audit                                                                                                                                                                                                                | User                             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                  | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Keratomileusis, LLT: LASIK eye surgery - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 04 Sep 2020 18:28:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                         | Coder Import (b) (4)<br>(b) (4)  | 04 Sep 2020 18:28:39 |
| Data point term sent to Coder                                                                                                                                                                                        | System                           | 04 Sep 2020 18:27:44 |
| User entered 'lasik'                                                                                                                                                                                                 | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:27:37 |

US3732262

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 2010' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:27:37 |

US3732262

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:27:37 |

US3732262

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition ongoing at study entry](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User entered 'No (N)' | Lauren Arnett (b) (4) | 04 Sep 2020 18:27:37 |
|                       | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'un UNK 2010' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:27:37 |



US3732262

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 11:12:45**

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4) | 04 Sep 2020 18:27:37 |
|                     | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 04 Sep 2020 18:27:37 |

US3732262

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2010' | System | 04 Sep 2020 18:27:37 |

US3732262

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 04 Sep 2020 18:27:37 |

US3732262

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2010' | System | 04 Sep 2020 18:27:37 |

US3732262

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:12:45

[Condition](#)

| Audit                                                                                                                                                             | User                             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                               | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Social issues NEC, PT: Substance use, LLT: Marijuana use - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 05 Sep 2020 17:53:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                           | Coder Import (b) (4)<br>(b) (4)  | 05 Sep 2020 17:53:40 |
| Data point term sent to Coder                                                                                                                                     | System                           | 04 Sep 2020 18:28:45 |
| User entered 'marijuana use - oral'                                                                                                                               | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:28:02 |

US3732262

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'un May 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:28:02 |

US3732262

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:28:02 |



US3732262

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition ongoing at study entry](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:50:18 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:28:02 |

US3732262

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User entered empty. | Lauren Arnett (b) (4) | 04 Sep 2020 18:28:02 |
|                     | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 11:12:45**

[Stop date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 23 Oct 2020 22:50:18 |
| User entered '0'    | Lauren Arnett (b) (4) | 04 Sep 2020 18:28:02 |
|                     | (b) (4)               |                      |

US3732262

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'May 2020' | System | 04 Sep 2020 18:28:02 |

US3732262

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 04 Sep 2020 18:28:02 |

US3732262

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:28:02 |

US3732262

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:28:02 |

US3732262

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:12:45

[Condition](#)

| Audit                                                                                                                                                                                          | User                            | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User closed query 'Per Medical HX Log; Please add "Left Sprained Ankle UK/MAR/2020-?"' (Site from CRA).                                                                                        | (b) (4), (b) (6)                | 06 Nov 2020 22:36:50 |
| Query 'Per Medical HX Log; Please add "Left Sprained Ankle UK/MAR/2020-?"' answered with 'updated' (Site from CRA).                                                                            | (b) (4), (b) (6)                | 05 Nov 2020 19:19:11 |
| DataPoint Verified.                                                                                                                                                                            | (b) (4), (b) (6)                | 23 Oct 2020 22:50:18 |
| User opened query 'Per Medical HX Log; Please add "Left Sprained Ankle UK/MAR/2020-?"' (Site from CRA).                                                                                        | (b) (4), (b) (6)                | 23 Oct 2020 22:48:35 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 13 Oct 2020 22:13:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                   | Coder Import (b) (4)<br>(b) (4) | 13 Oct 2020 22:13:24 |
| Data point term sent to Coder                                                                                                                                                                  | System                          | 13 Oct 2020 22:12:36 |
| User entered 'HYPERTENSION'                                                                                                                                                                    | (b) (4), (b) (6)                | 13 Oct 2020 22:12:13 |



US3732262

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 22:50:18 |
| User entered 'UN UNK 2014' | (b) (4), (b) (6) | 13 Oct 2020 22:12:13 |

US3732262

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 22:50:18 |
| User entered '0'    | (b) (4), (b) (6) | 13 Oct 2020 22:12:13 |

US3732262

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 23 Oct 2020 22:50:18 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Oct 2020 22:12:13 |

US3732262

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 22:50:18 |
| User entered empty. | (b) (4), (b) (6) | 13 Oct 2020 22:12:13 |

US3732262

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 11:12:45**

[Stop date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 22:50:18 |
| User entered '0'    | (b) (4), (b) (6) | 13 Oct 2020 22:12:13 |

US3732262

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 13 Oct 2020 22:12:13 |

US3732262

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2014' | System | 13 Oct 2020 22:12:13 |

US3732262

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Oct 2020 22:12:13 |



US3732262

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Oct 2020 22:12:13 |

US3732262

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:12:45

[Condition](#)

| Audit                                                                                                                                                                                                         | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                           | (b) (4), (b) (6)                | 06 Nov 2020 22:38:17 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament sprain, LLT: Sprained ankle - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 06 Nov 2020 06:12:32 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                       | Coder Import (b) (4)<br>(b) (4) | 06 Nov 2020 06:12:32 |
| Data point term sent to Coder                                                                                                                                                                                 | System                          | 05 Nov 2020 19:20:30 |
| User entered 'Left Sprained Ankle'                                                                                                                                                                            | (b) (4), (b) (6)                | 05 Nov 2020 19:19:35 |

US3732262

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 06 Nov 2020 22:38:17 |
| User entered 'un Mar 2020' | (b) (4), (b) (6) | 05 Nov 2020 19:19:35 |

US3732262

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 22:38:17 |
| User entered '0'    | (b) (4), (b) (6) | 05 Nov 2020 19:19:35 |

US3732262

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:38:17 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 05 Nov 2020 19:19:35 |

US3732262

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 22:38:17 |
| User entered empty. | (b) (4), (b) (6) | 05 Nov 2020 19:19:35 |

US3732262

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 11:12:45**

[Stop date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 22:38:17 |
| User entered '0'    | (b) (4), (b) (6) | 05 Nov 2020 19:19:35 |

US3732262

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Mar 2020' | System | 05 Nov 2020 19:19:35 |



US3732262

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 05 Nov 2020 19:19:35 |

US3732262

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 19:19:35 |

US3732262

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 19:19:35 |

US3732262

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:12:45

[Condition](#)

| Audit                                                                                                                                                                                                                                     | User                 | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                       | (b) (4), (b) (6)     | 06 Nov 2020 22:38:17 |
| User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation and uterine bleeding NEC, PT: Dysmenorrhoea, LLT: Menstrual cramps - version MedDRA\23.0. | Coder Import (b) (4) | 05 Nov 2020 19:21:23 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                               | (b) (4)              | 05 Nov 2020 19:21:23 |
| Data point term sent to Coder                                                                                                                                                                                                             | System               | 05 Nov 2020 19:20:32 |
| User entered 'Menstrual Cramps'                                                                                                                                                                                                           | (b) (4), (b) (6)     | 05 Nov 2020 19:20:29 |

US3732262

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 06 Nov 2020 22:38:17 |
| User entered 'un UNK 2014' | (b) (4), (b) (6) | 05 Nov 2020 19:20:29 |

US3732262

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 22:38:17 |
| User entered '0'    | (b) (4), (b) (6) | 05 Nov 2020 19:20:29 |

US3732262

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 11:12:45**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:38:17 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 05 Nov 2020 19:20:29 |

US3732262

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 22:38:17 |
| User entered empty. | (b) (4), (b) (6) | 05 Nov 2020 19:20:29 |



US3732262

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 11:12:45**

[Stop date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 22:38:17 |
| User entered '0'    | (b) (4), (b) (6) | 05 Nov 2020 19:20:29 |

US3732262

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 05 Nov 2020 19:20:29 |

US3732262

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2014' | System | 05 Nov 2020 19:20:29 |

US3732262

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 19:20:29 |

US3732262

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 19:20:29 |

US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Were vital signs assessed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:10 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:06 |

US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:10 |
| User entered '02 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:06 |

US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:10 |
| User entered '15:09' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:06 |



US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 15:09' | System | 04 Sep 2020 18:30:06 |

US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)      | 23 Oct 2020 22:51:10 |
| User entered '161.6' cm   | Lauren Arnett (b) (4) | 04 Sep 2020 18:30:06 |
| DataPoint set to visible. | (b) (4)<br>System     | 02 Sep 2020 23:18:51 |

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)      | 23 Oct 2020 22:51:10 |
| User entered '81.2' kg    | Lauren Arnett (b) (4) | 04 Sep 2020 18:30:06 |
| DataPoint set to visible. | (b) (4)<br>System     | 02 Sep 2020 23:18:51 |

US3732262

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

BMI (xxx.x)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered '31.09377'   | System | 04 Sep 2020 18:30:06 |
| DataPoint set to visible. | System | 02 Sep 2020 23:18:51 |

US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[BMI units](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered 'kg/m2'      | System | 04 Sep 2020 18:30:06 |
| DataPoint set to visible. | System | 02 Sep 2020 23:18:51 |

US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                                    | User                             | Time (GMT)           |
|------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:10 |
| User entered missing code ND - Not Done. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:06 |

US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Route of measurement](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:10 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:06 |

US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[If Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:10 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:06 |



US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Pulse \(xxx\)](#)

| Audit                                    | User                             | Time (GMT)           |
|------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:10 |
| User entered missing code ND - Not Done. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:06 |

US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 04 Sep 2020 18:30:06 |

US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                                    | User                             | Time (GMT)           |
|------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:10 |
| User entered missing code ND - Not Done. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:06 |

US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 04 Sep 2020 18:30:06 |

US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                                    | User                             | Time (GMT)           |
|------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:10 |
| User entered missing code ND - Not Done. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:06 |

US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 04 Sep 2020 18:30:06 |

US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                                    | User                             | Time (GMT)           |
|------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:10 |
| User entered missing code ND - Not Done. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:06 |

US3732262

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 04 Sep 2020 18:30:06 |



US3732262

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 11:12:45**

[Was the physical examination performed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:19 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:13 |

US3732262

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 11:12:45**

[Date of examination \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:19 |
| User entered '02 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:13 |

US3732262

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 11:12:45**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:29 |
| User entered '02 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:29 |

US3732262

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:29 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:29 |

US3732262

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 11:12:45**

[If No, what is the reason?](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:29 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:29 |

US3732262

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 11:12:45**

[If Partner medically sterile or Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:29 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:29 |

US3732262

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 11:12:45**

[If Surgically sterile, date of surgery \(dd MMM yyyy\)](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:29 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:29 |

US3732262

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 11:12:45**

[Date of surgery unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:29 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:29 |



US3732262

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:29 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:29 |

US3732262

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 11:12:45**

[Date of last menstruation unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:29 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:29 |

US3732262

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 11:12:45**

[Was the pregnancy test performed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:52 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:50 |

US3732262

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 11:12:45**

[Date of test \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:52 |
| User entered '02 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:50 |

US3732262

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 11:12:45**

[Test performed](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:52 |
| User entered 'Urine (URINE)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:50 |

US3732262

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 11:12:45**

[Result](#)

| Audit                              | User                             | Time (GMT)           |
|------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:52 |
| User entered 'Negative (NEGATIVE)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:50 |

US3732262

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 11:12:45**

[Was FSH sample collected?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:52 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:50 |

US3732262

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 11:12:45**

[Collection date](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:52 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:50 |



US3732262

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 11:12:45**

[Collection time](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:51:52 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:30:50 |

US3732262

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:30:50 |

US3732262

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 11:12:45**

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 23 Oct 2020 22:52:28 |
| User entered 'No (N)' | Lauren Arnett (b) (4) | 04 Sep 2020 18:31:20 |
|                       | (b) (4)               |                      |



US3732262

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:45

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

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:45

[Other](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:45

[Specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 11:12:45**

**No Risk Identified**

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |



US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:45

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:45

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:45

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:45

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered '1'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:45

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 11:12:45**

**Other**

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:12:45

[Specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:28 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:31:20 |

US3732262

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:45

[Was this visit performed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:45 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:33:06 |



US3732262

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:45

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:45 |
| User entered '02 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:33:06 |

US3732262

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:12:45

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

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                 | 23 Oct 2020 22:52:45 |
| User entered 'Clinic (Clinic)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:33:06 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 04 Sep 2020 18:33:06 |

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:45

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:53:09 |
| User entered '02 SEP 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 22:39:23 |

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:45

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

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:53:09 |
| User entered '111299' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 22:39:23 |

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                 | User                             | Time (GMT)           |
|-------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)                 | 23 Oct 2020 22:53:09 |
| User entered '>=18 and <65 years and not at risk (1)' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 22:39:23 |

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                        | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                          | (b) (4), (b) (6)                 | 23 Oct 2020 22:53:09 |
| User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).               | (b) (4), (b) (6)                 | 04 Sep 2020 23:18:22 |
| Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'complete ' (Site from DM). | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:33:36 |
| User entered 'No (N)'                                                                                                                                                        | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:33:28 |
| User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).               | (b) (4), (b) (6)                 | 04 Sep 2020 12:52:33 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:53:09 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:33:28 |



US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:45

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

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:53:09 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:33:28 |

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:45

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

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:53:09 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:33:28 |

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:45

[Liver Disease](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:53:09 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:33:28 |

US3732262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                        | User             | Time (GMT)           |
|----------------------------------------------|------------------|----------------------|
| DataPoint Verified.                          | (b) (4), (b) (6) | 23 Oct 2020 22:53:09 |
| User entered 'No (N)'                        | (b) (4), (b) (6) | 14 Oct 2020 16:55:30 |
| Amendment Manager: DataPoint set to visible. | System           | 19 Sep 2020 05:03:15 |
| Amendment Manager inserted this DataPoint.   | System           | 19 Sep 2020 05:03:13 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:45

Height

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | User                             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)                 | 23 Oct 2020 22:53:36 |
| User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).              | (b) (4), (b) (6)                 | 16 Oct 2020 15:42:08 |
| Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'Updated.' (Site from DM). | (b) (4), (b) (6)                 | 14 Oct 2020 16:54:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)                 | 14 Oct 2020 16:54:33 |
| User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).              | (b) (4), (b) (6)                 | 21 Sep 2020 14:30:33 |
| User entered empty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:45

[Weight](#)

| Audit                                                                       | User                             | Time (GMT)           |
|-----------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                         | (b) (4), (b) (6)                 | 23 Oct 2020 22:53:38 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)                 | 14 Oct 2020 16:54:41 |
| User entered empty.                                                         | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:45

Height

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | User                             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)                 | 23 Oct 2020 22:53:36 |
| User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).              | (b) (4), (b) (6)                 | 16 Oct 2020 15:42:08 |
| Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'Updated.' (Site from DM). | (b) (4), (b) (6)                 | 14 Oct 2020 16:54:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)                 | 14 Oct 2020 16:54:33 |
| User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).              | (b) (4), (b) (6)                 | 21 Sep 2020 14:30:33 |
| User entered empty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:45

[Weight](#)

| Audit                                                                       | User                             | Time (GMT)           |
|-----------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                         | (b) (4), (b) (6)                 | 23 Oct 2020 22:53:38 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)                 | 14 Oct 2020 16:54:41 |
| User entered empty.                                                         | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |



US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:45

[Timepoint](#)

| Audit                                            | User                             | Time (GMT)           |
|--------------------------------------------------|----------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:45

[Were vital signs assessed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:45

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered '02 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:45

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered '15:09' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 15:09' | System | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:45

Temperature (xxx.x)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered '99.0' F | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:45

[Route of measurement](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered 'Oral (Oral)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:45

[If Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |



US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:45

[Pulse \(xxx\)](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered '95'   | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 11:12:45**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:45

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered '14'   | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 11:12:45**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:45

Systolic Blood Pressure (xxx)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered '136'  | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 11:12:45**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:12:45

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered '85'   | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 11:12:45**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 04 Sep 2020 18:35:00 |



US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:45

Height

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | User                             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)                 | 23 Oct 2020 22:53:36 |
| User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).              | (b) (4), (b) (6)                 | 16 Oct 2020 15:42:08 |
| Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'Updated.' (Site from DM). | (b) (4), (b) (6)                 | 14 Oct 2020 16:54:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)                 | 14 Oct 2020 16:54:33 |
| User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).              | (b) (4), (b) (6)                 | 21 Sep 2020 14:30:33 |
| User entered empty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:12:45

[Weight](#)

| Audit                                                                       | User                             | Time (GMT)           |
|-----------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                         | (b) (4), (b) (6)                 | 23 Oct 2020 22:53:38 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)                 | 14 Oct 2020 16:54:41 |
| User entered empty.                                                         | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:45

[Timepoint](#)

| Audit                                              | User                             | Time (GMT)           |
|----------------------------------------------------|----------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:45

[Were vital signs assessed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:45

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered '02 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:45

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered '16:47' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 16:47' | System | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:45

Temperature (xxx.x)

| Audit                                                                                                                                                                                                                                                                      | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                        | (b) (4), (b) (6)      | 23 Oct 2020 22:54:12 |
| User closed query 'Temperature is not less than 38.0 C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' (Site from System).                                                                    | (b) (4), (b) (6)      | 04 Sep 2020 23:18:46 |
| Query 'Temperature is not less than 38.0 C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' answered with 'correct as is, as this is post-dose and post IP administration' (Site from System). | Lauren Arnett (b) (4) | 04 Sep 2020 18:36:58 |
| User opened query 'Temperature is not less than 38.0 System C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' (Site from System).                                                             | (b) (4)               | 04 Sep 2020 18:35:00 |
| User entered '100.5' F                                                                                                                                                                                                                                                     | Lauren Arnett (b) (4) | 04 Sep 2020 18:35:00 |



US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:45

[Route of measurement](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered 'Oral (Oral)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:45

[If Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:45

[Pulse \(xxx\)](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered '92'   | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 11:12:45**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:45

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered '16'   | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 11:12:45**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:45

Systolic Blood Pressure (xxx)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered '122'  | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 11:12:45**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 04 Sep 2020 18:35:00 |



US3732262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:12:45

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:12 |
| User entered '93'   | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:35:00 |

US3732262

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 11:12:45**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 04 Sep 2020 18:35:00 |

US3732262

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:45

[Was the physical examination performed?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:49 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:10 |

US3732262

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:45

Date of examination (*dd MMM yyyy*)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:49 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:10 |

US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:12:45

[Was the pregnancy test performed?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:57 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:14 |

US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:12:45

Date of test (dd MMM yyyy)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:57 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:14 |

US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:12:45

[Test performed](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:57 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:14 |

US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:12:45

[Result](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:57 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:14 |



US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:12:45

[Was FSH sample collected?](#)

| Audit                                                                                           | User                             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                             | (b) (4), (b) (6)                 | 06 Nov 2020 22:38:52 |
| User closed query 'per CDM: please select yes or no for this field' (Site from DM).             | (b) (4), (b) (6)                 | 06 Nov 2020 04:11:49 |
| Query 'per CDM: please select yes or no for this field' answered with 'updated' (Site from DM). | (b) (4), (b) (6)                 | 05 Nov 2020 19:08:19 |
| DataPoint Un-verified.                                                                          | (b) (4), (b) (6)                 | 05 Nov 2020 19:08:12 |
| User entered 'No (N)' reason for change: Data Entry Error                                       | (b) (4), (b) (6)                 | 05 Nov 2020 19:08:12 |
| User opened query 'per CDM: please select yes or no for this field' (Site from DM).             | (b) (4), (b) (6)                 | 04 Nov 2020 15:22:15 |
| DataPoint Verified.                                                                             | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:57 |
| User entered empty.                                                                             | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:14 |

US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:12:45

[Collection date](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:57 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:14 |

US3732262

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:12:45

[Collection time](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:54:57 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:14 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:37:14 |

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:45

[Was study treatment given?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:55:18 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 02 Sep 2020 23:19:12 |

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:45

[If No, reason not given](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:55:18 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:55:18 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 11:12:45**

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 02 Sep 2020 23:19:12 |



US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:45

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:55:18 |
| User entered '02 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 02 Sep 2020 23:19:12 |

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:45

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

| Audit                | User                  | Time (GMT)           |
|----------------------|-----------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)      | 23 Oct 2020 22:55:18 |
| User entered '16:17' | Lauren Arnett (b) (4) | 02 Sep 2020 23:19:12 |
|                      | (b) (4)               |                      |

US3732262

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 16:17' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:45

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

| Audit                              | User                             | Time (GMT)           |
|------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6)                 | 23 Oct 2020 22:55:18 |
| User entered 'Left Arm (LEFT ARM)' | Lauren Arnett (b) (4)<br>(b) (4) | 02 Sep 2020 23:19:12 |

US3732262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:12:45

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 22:55:18 |
| User entered 'ONCE' | System           | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:45

[Was the sample collected?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:55:33 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:30 |

US3732262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:45

Collection date (dd MMM yyyy)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:55:33 |
| User entered '02 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:30 |



US3732262

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Collection time \(00:00-23:59\)](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 23 Oct 2020 22:55:33 |
| User entered '15:59' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:30 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 15:59' | System | 04 Sep 2020 18:37:30 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 22:55:48 |
| User entered '02 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:56 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Lab Test](#)

| Audit                                                        | User                  | Time (GMT)           |
|--------------------------------------------------------------|-----------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Lauren Arnett (b) (4) | 04 Sep 2020 18:37:56 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Was the sample collected?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:55:48 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:56 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Collection time \(00:00 - 23:59\)](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 23 Oct 2020 22:55:48 |
| User entered '15:38' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:56 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 15:38' | System | 04 Sep 2020 18:37:56 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Lab Test](#)

| Audit                                                        | User                  | Time (GMT)           |
|--------------------------------------------------------------|-----------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Lauren Arnett (b) (4) | 04 Sep 2020 18:37:56 |



US3732262

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Was the sample collected?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 22:55:48 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:56 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Collection time \(00:00 - 23:59\)](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 22:55:48 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:37:56 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:37:56 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 22:55:58 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:38:02 |

US3732262

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Sep 2020 18:38:02 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:51:29', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4cad4be-3202-4c2f-99fb-5b9929540dd8' | System | 02 Sep 2020 23:53:11 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 02 Sep 2020 23:53:11 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

Please record your **TEMPERATURE in °F**

| Audit                                                                                                                                                                                                                                                                               | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:52:09', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4cad4be-3202-4c2f-99fb-5b9929540dd8' User entered '100.5' | System | 02 Sep 2020 23:53:11 |
|                                                                                                                                                                                                                                                                                     | System | 02 Sep 2020 23:53:11 |



US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:53:01', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4cad4be-3202-4c2f-99fb-5b9929540dd8' | System | 02 Sep 2020 23:53:11 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 23:53:11 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:53:08', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4cad4be-3202-4c2f-99fb-5b9929540dd8' | System | 02 Sep 2020 23:53:11 |
| User entered '02 Sep 2020 16:53'                                                                                                                                                                                                                               | System | 02 Sep 2020 23:53:11 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 16:37' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 19:07' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:23:19', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '4db8af9a-8776-4f17-af42-a2cf02fe6af4' | System | 03 Sep 2020 05:23:43 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 05:23:43 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:23:24', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '4db8af9a-8776-4f17-af42-a2cf02fe6af4' | System | 03 Sep 2020 05:23:43 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 05:23:43 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:23:40', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '4db8af9a-8776-4f17-af42-a2cf02fe6af4' | System | 03 Sep 2020 05:23:43 |
| User entered '02 Sep 2020 22:23'                                                                                                                                                                                                                               | System | 03 Sep 2020 05:23:43 |



US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 20:02' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 2' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:12:45

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:00:27', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1f8d0dea-e23b-47ea-80ad-366dc99897e9' | System | 03 Sep 2020 19:04:02 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 03 Sep 2020 19:04:02 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:12:45

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:03:48', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1f8d0dea-e23b-47ea-80ad-366dc99897e9' | System | 03 Sep 2020 19:04:02 |
| User entered '99.5'                                                                                                                                                                                                                                            | System | 03 Sep 2020 19:04:02 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:03:53', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1f8d0dea-e23b-47ea-80ad-366dc99897e9' | System | 03 Sep 2020 19:04:02 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 19:04:02 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:03:59', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1f8d0dea-e23b-47ea-80ad-366dc99897e9' User entered '03 Sep 2020 12:03' | System | 03 Sep 2020 19:04:02 |
|                                                                                                                                                                                                                                                                                                 | System | 03 Sep 2020 19:04:02 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |



US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 3' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:12:45

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:01:56', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '64bd3200-4b3e-4da1-adba-9e6530ee17e2' | System | 04 Sep 2020 23:03:28 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 04 Sep 2020 23:03:28 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:12:45

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:02:53', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '64bd3200-4b3e-4da1-adba-9e6530ee17e2' User entered '98.1' | System | 04 Sep 2020 23:03:28 |
|                                                                                                                                                                                                                                                                                    | System | 04 Sep 2020 23:03:28 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:02:57', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '64bd3200-4b3e-4da1-adba-9e6530ee17e2' | System | 04 Sep 2020 23:03:28 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 04 Sep 2020 23:03:28 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:12:45

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 'con meds updated for e-diary reported headache, does not meet reporting criteria for AE or true AR' (Site from System). | (b) (4), (b) (6)      | 14 Sep 2020 13:33:29 |
| 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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:03:17', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '64bd3200-4b3e-4da1-adba-9e6530ee17e2' User entered '1'                                                                                       | Lauren Arnett (b) (4) | 11 Sep 2020 17:13:42 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | System                | 04 Sep 2020 23:03:28 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | System                | 04 Sep 2020 23:03:28 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | System                | 04 Sep 2020 23:03:28 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:12:45

To **PREVENT** pain or fever from occurring

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:03:17', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '64bd3200-4b3e-4da1-adba-9e6530ee17e2' | System | 04 Sep 2020 23:03:28 |
| User entered '0'                                                                                                                                                                                                                                               | System | 04 Sep 2020 23:03:28 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:12:45

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:03:26', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '64bd3200-4b3e-4da1-adba-9e6530ee17e2' | System | 04 Sep 2020 23:03:28 |
| User entered '04 Sep 2020 16:03'                                                                                                                                                                                                                               | System | 04 Sep 2020 23:03:28 |



US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 4' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:12:45

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:13:41', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '97ab81f0-d94b-4405-826a-4653ac2c61d7' | System | 06 Sep 2020 02:16:58 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 06 Sep 2020 02:16:58 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:12:45

Please record your **TEMPERATURE in °F**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:16:20', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '97ab81f0-d94b-4405-826a-4653ac2c61d7' | System | 06 Sep 2020 02:16:58 |
| User entered '98.4'                                                                                                                                                                                                                                            | System | 06 Sep 2020 02:16:58 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:16:50', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '97ab81f0-d94b-4405-826a-4653ac2c61d7' | System | 06 Sep 2020 02:16:58 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Sep 2020 02:16:58 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:16:55', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '97ab81f0-d94b-4405-826a-4653ac2c61d7' | System | 06 Sep 2020 02:16:58 |
| User entered '05 Sep 2020 19:16'                                                                                                                                                                                                                               | System | 06 Sep 2020 02:16:58 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |



US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 5' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:12:45

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:19:36', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'cc55ef36-a1bd-4660-9e2a-df86eaf0c2ad' | System | 06 Sep 2020 20:24:34 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 06 Sep 2020 20:24:34 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:12:45

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:24:22', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'cc55ef36-a1bd-4660-9e2a-df86eaf0c2ad' | System | 06 Sep 2020 20:24:34 |
| User entered '99.0'                                                                                                                                                                                                                                            | System | 06 Sep 2020 20:24:34 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:24:26', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'cc55ef36-a1bd-4660-9e2a-df86eaf0c2ad' | System | 06 Sep 2020 20:24:34 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Sep 2020 20:24:34 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:24:31', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'cc55ef36-a1bd-4660-9e2a-df86eaf0c2ad' | System | 06 Sep 2020 20:24:34 |
| User entered '06 Sep 2020 13:24'                                                                                                                                                                                                                               | System | 06 Sep 2020 20:24:34 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |



US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 6' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:12:45

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:34:59', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'b5824645-8364-4201-9ad4-d7bc67b50e13' | System | 07 Sep 2020 23:37:07 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 07 Sep 2020 23:37:07 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:12:45

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:36:53', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'b5824645-8364-4201-9ad4-d7bc67b50e13' | System | 07 Sep 2020 23:37:07 |
| User entered '98.3'                                                                                                                                                                                                                                            | System | 07 Sep 2020 23:37:07 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:36:57', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'b5824645-8364-4201-9ad4-d7bc67b50e13' | System | 07 Sep 2020 23:37:07 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Sep 2020 23:37:07 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:12:45

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'b5824645-8364-4201-9ad4-d7bc67b50e13' | System | 07 Sep 2020 23:37:07 |
| User entered '07 Sep 2020 16:37'                                                                                                                                                                                                                               | System | 07 Sep 2020 23:37:07 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 7' | System | 02 Sep 2020 23:19:12 |



US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:12:45

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T17:21:01', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ad76e484-162b-46db-8a7a-75b6d818887f' | System | 09 Sep 2020 00:22:25 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 09 Sep 2020 00:22:25 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:12:45

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T17:22:06', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ad76e484-162b-46db-8a7a-75b6d818887f' | System | 09 Sep 2020 00:22:25 |
| User entered '98.6'                                                                                                                                                                                                                                            | System | 09 Sep 2020 00:22:25 |

US3732262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T17:22:14', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ad76e484-162b-46db-8a7a-75b6d818887f' | System | 09 Sep 2020 00:22:25 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 09 Sep 2020 00:22:25 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T17:22:21', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ad76e484-162b-46db-8a7a-75b6d818887f' | System | 09 Sep 2020 00:22:25 |
| User entered '08 Sep 2020 17:22'                                                                                                                                                                                                                               | System | 09 Sep 2020 00:22:25 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:12:45**

[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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:54:48', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd8db92e3-769d-43f8-92b7-4a93d4665895' | System | 02 Sep 2020 23:55:54 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 02 Sep 2020 23:55:54 |



US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:54:59', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd8db92e3-769d-43f8-92b7-4a93d4665895' | System | 02 Sep 2020 23:55:54 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 23:55:54 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:55:25', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd8db92e3-769d-43f8-92b7-4a93d4665895' | System | 02 Sep 2020 23:55:54 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 23:55:54 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:55:49', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd8db92e3-769d-43f8-92b7-4a93d4665895' | System | 02 Sep 2020 23:55:54 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 02 Sep 2020 23:55:54 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:55:52', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd8db92e3-769d-43f8-92b7-4a93d4665895' | System | 02 Sep 2020 23:55:54 |
| User entered '02 Sep 2020 16:55'                                                                                                                                                                                                                               | System | 02 Sep 2020 23:55:54 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 16:37' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 19:07' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:12:45**

[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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:24:22', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '8c04f015-06ee-4f43-94e1-8efcbde2b194' | System | 03 Sep 2020 05:25:04 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'                                                                                                                                                       | System | 03 Sep 2020 05:25:04 |



US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:24:29', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '8c04f015-06ee-4f43-94e1-8efcbde2b194' | System | 03 Sep 2020 05:25:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 05:25:04 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:24:34', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '8c04f015-06ee-4f43-94e1-8efcbde2b194' | System | 03 Sep 2020 05:25:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 05:25:04 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:12:45**

[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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:24:58', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '8c04f015-06ee-4f43-94e1-8efcbde2b194' | System | 03 Sep 2020 05:25:04 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'                                                                                                                                                  | System | 03 Sep 2020 05:25:04 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:25:02', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '8c04f015-06ee-4f43-94e1-8efcbde2b194' | System | 03 Sep 2020 05:25:04 |
| User entered '02 Sep 2020 22:25'                                                                                                                                                                                                                               | System | 03 Sep 2020 05:25:04 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 20:02' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 2' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:12:45**

[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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:46:02', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '36bce6f6-2dfe-46b1-9dde-6a5f86708443' | System | 03 Sep 2020 19:46:48 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'                                                                                                                                                       | System | 03 Sep 2020 19:46:48 |



US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:12:45

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:46:10', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '36bce6f6-2dfe-46b1-9dde-6a5f86708443' | System | 03 Sep 2020 19:46:48 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 19:46:48 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:46:15', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '36bce6f6-2dfe-46b1-9dde-6a5f86708443' | System | 03 Sep 2020 19:46:48 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 19:46:48 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:12:45

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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:46:42', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '36bce6f6-2dfe-46b1-9dde-6a5f86708443' | System | 03 Sep 2020 19:46:48 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'                                                                                                                                                  | System | 03 Sep 2020 19:46:48 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:46:45', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '36bce6f6-2dfe-46b1-9dde-6a5f86708443' | System | 03 Sep 2020 19:46:48 |
| User entered '03 Sep 2020 12:46'                                                                                                                                                                                                                               | System | 03 Sep 2020 19:46:48 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 3' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:12:45**

[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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:04:49', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd329c3bc-9d41-4799-acbb-fead2725cd2c' | System | 04 Sep 2020 23:05:38 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'                                                                                                                                                       | System | 04 Sep 2020 23:05:38 |



US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:12:45

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:04:54', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd329c3bc-9d41-4799-acbb-fead2725cd2c' | System | 04 Sep 2020 23:05:38 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Sep 2020 23:05:38 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:04:59', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd329c3bc-9d41-4799-acbb-fead2725cd2c' | System | 04 Sep 2020 23:05:38 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Sep 2020 23:05:38 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:12:45**

[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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:05:20', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd329c3bc-9d41-4799-acbb-fead2725cd2c' | System | 04 Sep 2020 23:05:38 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 23:05:38 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:12:45

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:05:35', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd329c3bc-9d41-4799-acbb-fead2725cd2c' | System | 04 Sep 2020 23:05:38 |
| User entered '04 Sep 2020 16:05'                                                                                                                                                                                                                               | System | 04 Sep 2020 23:05:38 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 4' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:12:45**

[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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:03', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'f69f78f9-eac5-4117-b2d6-b54692fa50d6' | System | 06 Sep 2020 02:17:22 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 02:17:22 |



US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:12:45

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:08', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'f69f78f9-eac5-4117-b2d6-b54692fa50d6' | System | 06 Sep 2020 02:17:22 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Sep 2020 02:17:22 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:11', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'f69f78f9-eac5-4117-b2d6-b54692fa50d6' | System | 06 Sep 2020 02:17:22 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Sep 2020 02:17:22 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:12:45**

[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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:18', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'f69f78f9-eac5-4117-b2d6-b54692fa50d6' | System | 06 Sep 2020 02:17:22 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 02:17:22 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:20', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'f69f78f9-eac5-4117-b2d6-b54692fa50d6' | System | 06 Sep 2020 02:17:22 |
| User entered '05 Sep 2020 19:17'                                                                                                                                                                                                                               | System | 06 Sep 2020 02:17:22 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 5' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:12:45**

[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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:24:36', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7d07fecd-d481-4a3b-9ad7-6056eb91101b' | System | 06 Sep 2020 20:24:54 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 20:24:54 |



US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:12:45

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:24:43', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7d07fecd-d481-4a3b-9ad7-6056eb91101b' | System | 06 Sep 2020 20:24:54 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Sep 2020 20:24:54 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:24:46', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7d07fecd-d481-4a3b-9ad7-6056eb91101b' | System | 06 Sep 2020 20:24:54 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Sep 2020 20:24:54 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:12:45

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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:24:49', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7d07fecd-d481-4a3b-9ad7-6056eb91101b' | System | 06 Sep 2020 20:24:54 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 20:24:54 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:12:45

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:24:52', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7d07fecd-d481-4a3b-9ad7-6056eb91101b' | System | 06 Sep 2020 20:24:54 |
| User entered '06 Sep 2020 13:24'                                                                                                                                                                                                                               | System | 06 Sep 2020 20:24:54 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 6' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:12:45**

[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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:05', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '9a192026-9647-4d4c-b5da-f83295983002' | System | 07 Sep 2020 23:37:25 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 23:37:25 |



US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:12:45

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:10', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '9a192026-9647-4d4c-b5da-f83295983002' | System | 07 Sep 2020 23:37:25 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Sep 2020 23:37:25 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:14', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '9a192026-9647-4d4c-b5da-f83295983002' | System | 07 Sep 2020 23:37:25 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Sep 2020 23:37:25 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:12:45**

[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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:20', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '9a192026-9647-4d4c-b5da-f83295983002' | System | 07 Sep 2020 23:37:25 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 23:37:25 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:23', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '9a192026-9647-4d4c-b5da-f83295983002' | System | 07 Sep 2020 23:37:25 |
| User entered '07 Sep 2020 16:37'                                                                                                                                                                                                                               | System | 07 Sep 2020 23:37:25 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 7' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:12:45**

[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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:19', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '251b301a-d496-458a-898c-26fbbdba447a' User entered 'None (1)' | System | 08 Sep 2020 20:32:40 |
|                                                                                                                                                                                                                                                                                        | System | 08 Sep 2020 20:32:40 |



US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:12:45

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:22', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '251b301a-d496-458a-898c-26fbdbda447a' User entered 'No (N)' | System | 08 Sep 2020 20:32:40 |
|                                                                                                                                                                                                                                                                                      | System | 08 Sep 2020 20:32:40 |

US3732262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:12:45

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

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:26', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '251b301a-d496-458a-898c-26fbbdba447a' User entered 'No (N)' | System | 08 Sep 2020 20:32:40 |
|                                                                                                                                                                                                                                                                                      | System | 08 Sep 2020 20:32:40 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:12:45**

[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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:34', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '251b301a-d496-458a-898c-26fbbdba447a' | System | 08 Sep 2020 20:32:40 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 20:32:40 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:38', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '251b301a-d496-458a-898c-26fbdbda447a' User entered '08 Sep 2020 13:32' | System | 08 Sep 2020 20:32:40 |
|                                                                                                                                                                                                                                                                                                 | System | 08 Sep 2020 20:32:40 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:56:00', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '3fe1371c-7179-4604-821c-344667a6aa1a' User entered 'None (0)' | System | 02 Sep 2020 23:56:41 |
|                                                                                                                                                                                                                                                                                        | System | 02 Sep 2020 23:56:41 |



US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:56:05', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '3fe1371c-7179-4604-821c-344667a6aa1a' User entered 'None (0)' | System | 02 Sep 2020 23:56:41 |
|                                                                                                                                                                                                                                                                                        | System | 02 Sep 2020 23:56:41 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:56:13', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '3fe1371c-7179-4604-821c-344667a6aa1a' User entered 'None (0)' | System | 02 Sep 2020 23:56:41 |
|                                                                                                                                                                                                                                                                                        | System | 02 Sep 2020 23:56:41 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:56:17', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '3fe1371c-7179-4604-821c-344667a6aa1a' User entered 'None (0)' | System | 02 Sep 2020 23:56:41 |
|                                                                                                                                                                                                                                                                                        | System | 02 Sep 2020 23:56:41 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:56:22', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '3fe1371c-7179-4604-821c-344667a6aa1a' User entered 'None (0)' | System | 02 Sep 2020 23:56:41 |
|                                                                                                                                                                                                                                                                                        | System | 02 Sep 2020 23:56:41 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:56:24', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '3fe1371c-7179-4604-821c-344667a6aa1a' User entered 'None (0)' | System | 02 Sep 2020 23:56:41 |
|                                                                                                                                                                                                                                                                                        | System | 02 Sep 2020 23:56:41 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:56:35', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '3fe1371c-7179-4604-821c-344667a6aa1a' User entered 'No (N)' | System | 02 Sep 2020 23:56:41 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:12:45

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T16:56:38', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '3fe1371c-7179-4604-821c-344667a6aa1a' | System | 02 Sep 2020 23:56:41 |
| User entered '02 Sep 2020 16:56'                                                                                                                                                                                                                               | System | 02 Sep 2020 23:56:41 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 16:37' | System | 02 Sep 2020 23:19:12 |



US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 19:07' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:25:47', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '48adf5d3-898a-45fe-a60b-513f4d33e663' | System | 03 Sep 2020 05:28:27 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 03 Sep 2020 05:28:27 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:26:07', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '48adf5d3-898a-45fe-a60b-513f4d33e663' | System | 03 Sep 2020 05:28:27 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 03 Sep 2020 05:28:27 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:26:29', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '48adf5d3-898a-45fe-a60b-513f4d33e663' | System | 03 Sep 2020 05:28:27 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 03 Sep 2020 05:28:27 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:27:43', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '48adf5d3-898a-45fe-a60b-513f4d33e663' | System | 03 Sep 2020 05:28:27 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 03 Sep 2020 05:28:27 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:27:52', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '48adf5d3-898a-45fe-a60b-513f4d33e663' | System | 03 Sep 2020 05:28:27 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 05:28:27 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:28:04', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '48adf5d3-898a-45fe-a60b-513f4d33e663' | System | 03 Sep 2020 05:28:27 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 05:28:27 |



US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:28:22', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '48adf5d3-898a-45fe-a60b-513f4d33e663' | System | 03 Sep 2020 05:28:27 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 05:28:27 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:12:45

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-02T22:28:25', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '48adf5d3-898a-45fe-a60b-513f4d33e663' | System | 03 Sep 2020 05:28:27 |
| User entered '02 Sep 2020 22:28'                                                                                                                                                                                                                               | System | 03 Sep 2020 05:28:27 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 20:02' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 2' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:12:45

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:46:57', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1bb78657-d09d-454a-9759-5a6bf9bfacc4' | System | 03 Sep 2020 19:47:57 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 03 Sep 2020 19:47:57 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:12:45

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:47:06', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1bb78657-d09d-454a-9759-5a6bf9bfacc4' | System | 03 Sep 2020 19:47:57 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 03 Sep 2020 19:47:57 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:12:45

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:47:15', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1bb78657-d09d-454a-9759-5a6bf9bfacc4' | System | 03 Sep 2020 19:47:57 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 03 Sep 2020 19:47:57 |



US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:12:45

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:47:26', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1bb78657-d09d-454a-9759-5a6bf9bfacc4' | System | 03 Sep 2020 19:47:57 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 03 Sep 2020 19:47:57 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:12:45

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:47:30', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1bb78657-d09d-454a-9759-5a6bf9bfacc4' | System | 03 Sep 2020 19:47:57 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 19:47:57 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:12:45

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:47:33', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1bb78657-d09d-454a-9759-5a6bf9bfacc4' | System | 03 Sep 2020 19:47:57 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 19:47:57 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:12:45

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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:47:52', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1bb78657-d09d-454a-9759-5a6bf9bfacc4' | System | 03 Sep 2020 19:47:57 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 19:47:57 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:12:45

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-03T12:47:55', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1bb78657-d09d-454a-9759-5a6bf9bfacc4' | System | 03 Sep 2020 19:47:57 |
| User entered '03 Sep 2020 12:47'                                                                                                                                                                                                                               | System | 03 Sep 2020 19:47:57 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 3' | System | 02 Sep 2020 23:19:12 |



US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:12:45

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:05:50', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a73a336-ea0b-4c5a-9ac7-23195f9889f0' | System | 04 Sep 2020 23:08:18 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'                                                                                                                                                | System | 04 Sep 2020 23:08:18 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:12:45

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:05:57', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a73a336-ea0b-4c5a-9ac7-23195f9889f0' | System | 04 Sep 2020 23:08:18 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 23:08:18 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:12:45

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:06:03', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a73a336-ea0b-4c5a-9ac7-23195f9889f0' | System | 04 Sep 2020 23:08:18 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 23:08:18 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:12:45

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:06:11', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a73a336-ea0b-4c5a-9ac7-23195f9889f0' | System | 04 Sep 2020 23:08:18 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 23:08:18 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:12:45

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:06:15', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a73a336-ea0b-4c5a-9ac7-23195f9889f0' | System | 04 Sep 2020 23:08:18 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 23:08:18 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:12:45

CHILLS

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:08:01', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a73a336-ea0b-4c5a-9ac7-23195f9889f0' | System | 04 Sep 2020 23:08:18 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 23:08:18 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:12:45

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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:08:07', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a73a336-ea0b-4c5a-9ac7-23195f9889f0' | System | 04 Sep 2020 23:08:18 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Sep 2020 23:08:18 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-04T16:08:15', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '7a73a336-ea0b-4c5a-9ac7-23195f9889f0' User entered '04 Sep 2020 16:08' | System | 04 Sep 2020 23:08:18 |
|                                                                                                                                                                                                                                                                                                 | System | 04 Sep 2020 23:08:18 |



US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 4' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:12:45

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:36', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1eee1ee9-5d9d-48fb-91f8-f9770dc81364' | System | 06 Sep 2020 02:18:26 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'                                                                                                                                                | System | 06 Sep 2020 02:18:26 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:12:45

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:44', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1eee1ee9-5d9d-48fb-91f8-f9770dc81364' | System | 06 Sep 2020 02:18:26 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 02:18:26 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:12:45

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:47', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1eee1ee9-5d9d-48fb-91f8-f9770dc81364' | System | 06 Sep 2020 02:18:26 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 02:18:26 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:12:45

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:17:58', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1eee1ee9-5d9d-48fb-91f8-f9770dc81364' | System | 06 Sep 2020 02:18:26 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 02:18:26 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:12:45

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:18:14', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1eee1ee9-5d9d-48fb-91f8-f9770dc81364' | System | 06 Sep 2020 02:18:26 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'                                                                                                                                                                                      | System | 06 Sep 2020 02:18:26 |



US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:12:45

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:18:18', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1eee1ee9-5d9d-48fb-91f8-f9770dc81364' | System | 06 Sep 2020 02:18:26 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 02:18:26 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:12:45

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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:18:21', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1eee1ee9-5d9d-48fb-91f8-f9770dc81364' | System | 06 Sep 2020 02:18:26 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Sep 2020 02:18:26 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:12:45

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-05T19:18:24', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '1eee1ee9-5d9d-48fb-91f8-f9770dc81364' | System | 06 Sep 2020 02:18:26 |
| User entered '05 Sep 2020 19:18'                                                                                                                                                                                                                               | System | 06 Sep 2020 02:18:26 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 5' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:12:45

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:25:07', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ba9a3571-a382-4228-976f-256b1095ed4c' | System | 06 Sep 2020 20:25:46 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 06 Sep 2020 20:25:46 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:12:45

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:25:16', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ba9a3571-a382-4228-976f-256b1095ed4c' User entered 'None (0)' | System | 06 Sep 2020 20:25:46 |
|                                                                                                                                                                                                                                                                                        | System | 06 Sep 2020 20:25:46 |



US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:12:45

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:25:19', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ba9a3571-a382-4228-976f-256b1095ed4c' | System | 06 Sep 2020 20:25:46 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 20:25:46 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:12:45

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:25:20', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ba9a3571-a382-4228-976f-256b1095ed4c' | System | 06 Sep 2020 20:25:46 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 20:25:46 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:12:45

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:25:32', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ba9a3571-a382-4228-976f-256b1095ed4c' | System | 06 Sep 2020 20:25:46 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'                                                                                                                                                                                      | System | 06 Sep 2020 20:25:46 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:12:45

CHILLS

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:25:35', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ba9a3571-a382-4228-976f-256b1095ed4c' | System | 06 Sep 2020 20:25:46 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 20:25:46 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:12:45

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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:25:39', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ba9a3571-a382-4228-976f-256b1095ed4c' | System | 06 Sep 2020 20:25:46 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Sep 2020 20:25:46 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:12:45

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-06T13:25:41', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'ba9a3571-a382-4228-976f-256b1095ed4c' User entered '06 Sep 2020 13:25' | System | 06 Sep 2020 20:25:46 |
|                                                                                                                                                                                                                                                                                                 | System | 06 Sep 2020 20:25:46 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |



US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 6' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:12:45

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:36', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4299641-cdf7-43e7-a5fd-95fb79d4e54c' | System | 07 Sep 2020 23:38:24 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 07 Sep 2020 23:38:24 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:12:45

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:47', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4299641-cdf7-43e7-a5fd-95fb79d4e54c' | System | 07 Sep 2020 23:38:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 23:38:24 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:12:45

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:49', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4299641-cdf7-43e7-a5fd-95fb79d4e54c' | System | 07 Sep 2020 23:38:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 23:38:24 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:12:45

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:52', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4299641-cdf7-43e7-a5fd-95fb79d4e54c' | System | 07 Sep 2020 23:38:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 23:38:24 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:12:45

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:37:56', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4299641-cdf7-43e7-a5fd-95fb79d4e54c' | System | 07 Sep 2020 23:38:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 23:38:24 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:12:45

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:38:02', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4299641-cdf7-43e7-a5fd-95fb79d4e54c' | System | 07 Sep 2020 23:38:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 23:38:24 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:12:45

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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:38:16', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4299641-cdf7-43e7-a5fd-95fb79d4e54c' | System | 07 Sep 2020 23:38:24 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Sep 2020 23:38:24 |



US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-07T16:38:19', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'c4299641-cdf7-43e7-a5fd-95fb79d4e54c' | System | 07 Sep 2020 23:38:24 |
| User entered '07 Sep 2020 16:38'                                                                                                                                                                                                                               | System | 07 Sep 2020 23:38:24 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:12:45

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 7' | System | 02 Sep 2020 23:19:12 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:12:45

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:42', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '109f25a4-c2d8-4d36-83c9-378c119aa4f4' | System | 08 Sep 2020 20:33:22 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 20:33:22 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:12:45

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:47', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '109f25a4-c2d8-4d36-83c9-378c119aa4f4' | System | 08 Sep 2020 20:33:22 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 20:33:22 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:12:45

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:53', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '109f25a4-c2d8-4d36-83c9-378c119aa4f4' | System | 08 Sep 2020 20:33:22 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 20:33:22 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:12:45

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:32:59', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '109f25a4-c2d8-4d36-83c9-378c119aa4f4' | System | 08 Sep 2020 20:33:22 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 20:33:22 |



US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:12:45

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:33:03', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '109f25a4-c2d8-4d36-83c9-378c119aa4f4' | System | 08 Sep 2020 20:33:22 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 20:33:22 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:12:45

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:33:11', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '109f25a4-c2d8-4d36-83c9-378c119aa4f4' | System | 08 Sep 2020 20:33:22 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 20:33:22 |

US3732262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:12:45

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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:33:17', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '109f25a4-c2d8-4d36-83c9-378c119aa4f4' | System | 08 Sep 2020 20:33:22 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Sep 2020 20:33:22 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-09-08T13:33:19', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '109f25a4-c2d8-4d36-83c9-378c119aa4f4' | System | 08 Sep 2020 20:33:22 |
| User entered '08 Sep 2020 13:33'                                                                                                                                                                                                                               | System | 08 Sep 2020 20:33:22 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:00' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:12:45**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 02 Sep 2020 23:19:12 |

US3732262

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Was Contact Attempted?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 23 Oct 2020 22:57:06 |
| User entered 'Yes (Y)' | Linda Vega (b) (4)<br>(b) (4) | 10 Sep 2020 16:33:21 |

US3732262

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)              | 23 Oct 2020 22:57:06 |
| User entered '09 Sep 2020' | Linda Vega (b) (4)<br>(b) (4) | 10 Sep 2020 16:33:21 |



US3732262

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                          | Time (GMT)           |
|--------------------------------------------|-------------------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6)              | 23 Oct 2020 22:57:06 |
| User entered 'Contact Made (CONTACT MADE)' | Linda Vega (b) (4)<br>(b) (4) | 10 Sep 2020 16:33:21 |

US3732262

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)              | 23 Oct 2020 22:57:06 |
| User entered empty. | Linda Vega (b) (4)<br>(b) (4) | 10 Sep 2020 16:33:21 |

US3732262

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)              | 23 Oct 2020 22:57:15 |
| User entered 'Yes (Y)' | Linda Vega (b) (4)<br>(b) (4) | 10 Sep 2020 16:33:24 |

US3732262

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 10 Sep 2020 16:33:24 |

US3732262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:45

[Was Contact Attempted?](#)

| Audit                                                                                                                                                                                                           | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                             | (b) (4), (b) (6)      | 09 Nov 2020 22:32:49 |
| DataPoint Un-verified.                                                                                                                                                                                          | (b) (4), (b) (6)      | 06 Nov 2020 22:45:06 |
| DataPoint Verified.                                                                                                                                                                                             | (b) (4), (b) (6)      | 06 Nov 2020 22:39:28 |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                      | System                | 27 Oct 2020 18:56:59 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).                                                                                                                          | System                | 27 Oct 2020 18:56:59 |
| User entered 'No (N)' reason for change: Data Entry Error                                                                                                                                                       | Lauren Arnett (b) (4) | 27 Oct 2020 18:56:59 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                                                      | System                | 27 Oct 2020 18:55:38 |
| User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System). | System                | 27 Oct 2020 18:55:38 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                          | (b) (4), (b) (6)      | 27 Oct 2020 18:55:38 |
| User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System). | System                | 27 Oct 2020 18:55:15 |
| User entered 'No (N)'                                                                                                                                                                                           | (b) (4), (b) (6)      | 27 Oct 2020 18:55:15 |

US3732262

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 09 Nov 2020 22:32:49 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Nov 2020 22:45:06 |
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:39:28 |
| User entered empty.    | (b) (4), (b) (6) | 27 Oct 2020 18:55:15 |

US3732262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:45

[Please select one status for the follow-up contact](#)

| Audit                                                  | User                  | Time (GMT)           |
|--------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)      | 09 Nov 2020 22:32:49 |
| DataPoint Un-verified.                                 | (b) (4), (b) (6)      | 06 Nov 2020 22:45:06 |
| DataPoint Verified.                                    | (b) (4), (b) (6)      | 06 Nov 2020 22:39:28 |
| User entered empty; reason for change Data Entry Error | Lauren Arnett (b) (4) | 27 Oct 2020 18:56:59 |
| User entered 'Contact Not Made (CONTACT NOT MADE)'     | (b) (4), (b) (6)      | 27 Oct 2020 18:55:15 |

US3732262

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                                                            | User             | Time (GMT)           |
|------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                              | (b) (4), (b) (6) | 09 Nov 2020 22:32:49 |
| DataPoint Un-verified.                                           | (b) (4), (b) (6) | 06 Nov 2020 22:45:06 |
| DataPoint Verified.                                              | (b) (4), (b) (6) | 06 Nov 2020 22:39:28 |
| User entered 'Visit will be omitted due to Convalescent Period.' | (b) (4), (b) (6) | 27 Oct 2020 18:55:15 |



US3732262

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 09 Nov 2020 22:32:55 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Nov 2020 22:45:14 |
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:39:34 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 27 Oct 2020 18:57:48 |

US3732262

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 27 Oct 2020 18:57:48 |

US3732262

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 09 Nov 2020 22:33:19 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Nov 2020 22:45:24 |
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:39:52 |
| User entered 'No (N)'  | (b) (4), (b) (6) | 04 Nov 2020 18:57:25 |

US3732262

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 09 Nov 2020 22:33:19 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Nov 2020 22:45:24 |
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:39:52 |
| User entered empty.    | (b) (4), (b) (6) | 04 Nov 2020 18:57:25 |

US3732262

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Please select one status for the follow-up contact](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 09 Nov 2020 22:33:19 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Nov 2020 22:45:24 |
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:39:52 |
| User entered empty.    | (b) (4), (b) (6) | 04 Nov 2020 18:57:25 |

US3732262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:12:45

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                                                                                       | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                         | (b) (4), (b) (6) | 09 Nov 2020 23:09:00 |
| User entered 'Subject was in the Convalescent phase'<br>reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 22:46:17 |
| DataPoint Un-verified.                                                                      | (b) (4), (b) (6) | 09 Nov 2020 22:33:31 |
| DataPoint Verified.                                                                         | (b) (4), (b) (6) | 09 Nov 2020 22:33:19 |
| DataPoint Un-verified.                                                                      | (b) (4), (b) (6) | 06 Nov 2020 22:45:24 |
| DataPoint Verified.                                                                         | (b) (4), (b) (6) | 06 Nov 2020 22:39:52 |
| User entered empty.                                                                         | (b) (4), (b) (6) | 04 Nov 2020 18:57:25 |

US3732262

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                                                      | User             | Time (GMT)           |
|------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                        | (b) (4), (b) (6) | 09 Nov 2020 23:09:07 |
| DataPoint Un-verified.                                     | (b) (4), (b) (6) | 06 Nov 2020 22:45:32 |
| DataPoint Verified.                                        | (b) (4), (b) (6) | 06 Nov 2020 22:39:58 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 04 Nov 2020 18:57:53 |
| User entered 'No (N)'                                      | (b) (4), (b) (6) | 04 Nov 2020 18:57:12 |

US3732262

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

[Continuing Flag](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1'    | System | 04 Nov 2020 18:57:53 |
| User entered empty. | System | 04 Nov 2020 18:57:12 |



US3732262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:45

[Was this visit performed?](#)

| Audit                                                                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 09 Nov 2020 23:11:06 |
| User closed query 'Per CDM: As per CCGs p. 18 Scenario 4: Vital Signs Dosing, Physical Examination, Exposure and Immunogenicity Assessment forms should be completed accordingly. Kindly review and reconcile as appropriate. ' (Site from DM).                                                                                        | (b) (4), (b) (6) | 09 Nov 2020 15:08:35 |
| Query 'Per CDM: As per CCGs p. 18 Scenario 4: Vital Signs Dosing, Physical Examination, Exposure and Immunogenicity Assessment forms should be completed accordingly. Kindly review and reconcile as appropriate. ' answered with 'Correct as is. Visit not completed as subject entered into the Convalescent Phase ' (Site from DM). | (b) (4), (b) (6) | 06 Nov 2020 23:49:20 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                                                 | (b) (4), (b) (6) | 06 Nov 2020 22:45:43 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 06 Nov 2020 22:41:01 |
| User opened query 'Per CDM: As per CCGs p. 18 Scenario 4: Vital Signs Dosing, Physical Examination, Exposure and Immunogenicity Assessment forms should be completed accordingly. Kindly review and reconcile as appropriate. ' (Site from DM).                                                                                        | (b) (4), (b) (6) | 06 Nov 2020 13:33:02 |
| User entered 'No (N)'                                                                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 04 Nov 2020 18:58:04 |

US3732262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:45

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 09 Nov 2020 23:11:06 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Nov 2020 22:45:43 |
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:41:01 |
| User entered empty.    | (b) (4), (b) (6) | 04 Nov 2020 18:58:04 |

US3732262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:12:45

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 09 Nov 2020 23:11:06 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Nov 2020 22:45:43 |
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:41:01 |
| User entered empty.    | (b) (4), (b) (6) | 04 Nov 2020 18:58:04 |

US3732262

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 04 Nov 2020 18:58:04 |

US3732262

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 09 Nov 2020 23:11:42 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Nov 2020 22:46:19 |
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:41:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 04 Nov 2020 18:58:17 |

US3732262

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Nov 2020 18:58:17 |

US3732262

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 09 Nov 2020 23:32:30 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Nov 2020 22:46:40 |
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:41:42 |
| User entered 'No (N)'  | (b) (4), (b) (6) | 04 Nov 2020 19:12:08 |

US3732262

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 09 Nov 2020 23:32:30 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Nov 2020 22:46:40 |
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:41:42 |
| User entered empty.    | (b) (4), (b) (6) | 04 Nov 2020 19:12:08 |



US3732262

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Please select one status for the follow-up contact](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 09 Nov 2020 23:32:30 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Nov 2020 22:46:40 |
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:41:42 |
| User entered empty.    | (b) (4), (b) (6) | 04 Nov 2020 19:12:08 |

US3732262

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                                                                                       | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                         | (b) (4), (b) (6) | 09 Nov 2020 23:32:30 |
| User entered 'Subject was in the Convalescent Phase'<br>reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 23:17:09 |
| DataPoint Un-verified.                                                                      | (b) (4), (b) (6) | 06 Nov 2020 22:46:40 |
| DataPoint Verified.                                                                         | (b) (4), (b) (6) | 06 Nov 2020 22:41:42 |
| User entered empty.                                                                         | (b) (4), (b) (6) | 04 Nov 2020 19:12:08 |

US3732262

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 09 Nov 2020 23:32:36 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Nov 2020 22:46:51 |
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:41:47 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 04 Nov 2020 19:12:02 |

US3732262

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Nov 2020 19:12:02 |

US3732262

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Nov 2020 22:47:00 |
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:42:15 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 04 Nov 2020 19:12:34 |

US3732262

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Un-verified.     | (b) (4), (b) (6) | 06 Nov 2020 22:47:00 |
| DataPoint Verified.        | (b) (4), (b) (6) | 06 Nov 2020 22:42:15 |
| User entered '15 Oct 2020' | (b) (4), (b) (6) | 04 Nov 2020 19:12:34 |

US3732262

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                     | (b) (4), (b) (6) | 06 Nov 2020 22:47:00 |
| DataPoint Verified.                        | (b) (4), (b) (6) | 06 Nov 2020 22:42:15 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 04 Nov 2020 19:12:34 |

US3732262

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Nov 2020 22:47:00 |
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:42:15 |
| User entered empty.    | (b) (4), (b) (6) | 04 Nov 2020 19:12:34 |



US3732262

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Nov 2020 22:47:08 |
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:42:22 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 04 Nov 2020 19:12:39 |

US3732262

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Nov 2020 19:12:39 |

US3732262

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 04 Nov 2020 19:12:52 |

US3732262

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '22 Oct 2020' | (b) (4), (b) (6) | 04 Nov 2020 19:12:52 |

US3732262

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 04 Nov 2020 19:12:52 |

US3732262

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:12:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 04 Nov 2020 19:12:52 |

US3732262

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 04 Nov 2020 19:12:56 |

US3732262

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Nov 2020 19:12:56 |



US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

[Was this visit performed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:26:57 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '04 Nov 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:26:57 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:26:57 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 05 Nov 2020 19:26:57 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Were vital signs assessed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:27:27 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '04 Nov 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:27:27 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '14:38' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:27:27 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Nov 2020 14:38' | System | 05 Nov 2020 19:27:27 |



US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

Temperature (xxx.x)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| User entered '99.2' F | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:27:27 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Route of measurement](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered 'Oral (Oral)' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:27:27 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[If Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:27:27 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Pulse \(xxx\)](#)

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '86' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:27:27 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 05 Nov 2020 19:27:27 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '16' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:27:27 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 05 Nov 2020 19:27:27 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit              | User                             | Time (GMT)           |
|--------------------|----------------------------------|----------------------|
| User entered '134' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:27:27 |



US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 05 Nov 2020 19:27:27 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit             | User                             | Time (GMT)           |
|-------------------|----------------------------------|----------------------|
| User entered '88' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:27:27 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 05 Nov 2020 19:27:27 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 11:12:45**

[Was the physical examination performed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:27:39 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '04 Nov 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:27:39 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Was the sample collected?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:27:52 |

US3732262

**Folder:** Visit 3 Day 57 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 11:12:45

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered '04 Nov 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:27:52 |

US3732262

**Folder:** Visit 3 Day 57 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 11:12:45

[Collection time \(00:00-23:59\)](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered '14:52' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:27:52 |



US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Nov 2020 14:52' | System | 05 Nov 2020 19:27:52 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

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

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:28:06 |

US3732262

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:12:45**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Nov 2020 19:28:06 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 64' | System | 02 Sep 2020 23:19:12 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-05T17:59:29', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd40fb24f-e586-4dcb-9be4-73fae9ab2071' | System | 06 Nov 2020 02:00:25 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Nov 2020 02:00:25 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

Have you been exposed to someone with 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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-05T17:59:52', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd40fb24f-e586-4dcb-9be4-73fae9ab2071' | System | 06 Nov 2020 02:00:25 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Nov 2020 02:00:25 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-05T18:00:22', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'd40fb24f-e586-4dcb-9be4-73fae9ab2071' | System | 06 Nov 2020 02:00:25 |
| User entered '05 Nov 2020 18:00:22'                                                                                                                                                                                                                            | System | 06 Nov 2020 02:00:25 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 02 Sep 2020 23:19:12 |
| User entered '02 Nov 2020 00:01' | System | 02 Sep 2020 23:19:12 |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 02 Sep 2020 23:19:12 |
| User entered '06 Nov 2020 23:59' | System | 02 Sep 2020 23:19:12 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 71' | System | 02 Sep 2020 23:19:12 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-09T02:45:39', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'a9c67db1-3725-4e37-938b-f5d58d2001c8' User entered 'No (N)' | System | 09 Nov 2020 10:45:55 |
|                                                                                                                                                                                                                                                                                      | System | 09 Nov 2020 10:45:55 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

Have you been exposed to someone with 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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-09T02:44:51', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'a9c67db1-3725-4e37-938b-f5d58d2001c8' | System | 09 Nov 2020 10:45:55 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 09 Nov 2020 10:45:55 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-09T02:45:52', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: 'a9c67db1-3725-4e37-938b-f5d58d2001c8' User entered '09 Nov 2020 02:45:52' | System | 09 Nov 2020 10:45:55 |
|                                                                                                                                                                                                                                                                                                    | System | 09 Nov 2020 10:45:55 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 02 Sep 2020 23:19:12 |
| User entered '09 Nov 2020 00:01' | System | 02 Sep 2020 23:19:12 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 02 Sep 2020 23:19:12 |
| User entered '13 Nov 2020 23:59' | System | 02 Sep 2020 23:19:12 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 02 Sep 2020 23:19:12 |
| User entered 'Day 78' | System | 02 Sep 2020 23:19:12 |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-16T00:01:21', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '996fe8cb-a662-4689-812c-08530925071b' User entered 'No (N)' | System | 16 Nov 2020 08:01:49 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

Have you been exposed to someone with 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 (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-16T00:01:31', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '996fe8cb-a662-4689-812c-08530925071b' User entered 'No (N)' | System | 16 Nov 2020 08:01:49 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (451DEC7E-AD6A-4452-A688-58B149916272)', Time: '2020-11-16T00:01:46', User OID: 'PatientReportedOutcome (US3732262)', ODM File OID: '996fe8cb-a662-4689-812c-08530925071b' User entered '16 Nov 2020 00:01:46' | System | 16 Nov 2020 08:01:49 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 02 Sep 2020 23:19:12 |
| User entered '16 Nov 2020 00:01' | System | 02 Sep 2020 23:19:12 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 02 Sep 2020 23:19:12 |
| User entered '20 Nov 2020 23:59' | System | 02 Sep 2020 23:19:12 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 61' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '30 Oct 2020 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '03 Nov 2020 23:59' | System | 20 Nov 2020 03:00:44 |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 68' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '06 Nov 2020 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '10 Nov 2020 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 75' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '13 Nov 2020 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '17 Nov 2020 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '20 Nov 2020 00:01' | System | 20 Nov 2020 03:00:44 |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '24 Nov 2020 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '27 Nov 2020 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '01 Dec 2020 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '04 Dec 2020 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '08 Dec 2020 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 03:00:44 |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '11 Dec 2020 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '15 Dec 2020 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '18 Dec 2020 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '22 Dec 2020 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '25 Dec 2020 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '29 Dec 2020 23:59' | System | 20 Nov 2020 03:00:44 |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '01 Jan 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '05 Jan 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '08 Jan 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '12 Jan 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '15 Jan 2021 00:01' | System | 20 Nov 2020 03:00:44 |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '19 Jan 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '22 Jan 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '26 Jan 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '29 Jan 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '02 Feb 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 03:00:44 |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '05 Feb 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '09 Feb 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '12 Feb 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '16 Feb 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '19 Feb 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '23 Feb 2021 23:59' | System | 20 Nov 2020 03:00:44 |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '26 Feb 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '02 Mar 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 11:12:45

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '05 Mar 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '09 Mar 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '12 Mar 2021 00:01' | System | 20 Nov 2020 03:00:44 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '16 Mar 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '19 Mar 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '23 Mar 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '26 Mar 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '30 Mar 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 03:00:44 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '02 Apr 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '06 Apr 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '09 Apr 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '13 Apr 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '16 Apr 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '20 Apr 2021 23:59' | System | 20 Nov 2020 03:00:44 |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '23 Apr 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '27 Apr 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '30 Apr 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '04 May 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '07 May 2021 00:01' | System | 20 Nov 2020 03:00:44 |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '11 May 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '14 May 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '18 May 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '21 May 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '25 May 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 03:00:44 |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '28 May 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '01 Jun 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '04 Jun 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '08 Jun 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '11 Jun 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '15 Jun 2021 23:59' | System | 20 Nov 2020 03:00:44 |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '18 Jun 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '22 Jun 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '25 Jun 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '29 Jun 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 11:12:45

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '02 Jul 2021 00:01' | System | 20 Nov 2020 03:00:44 |



US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '06 Jul 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '09 Jul 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '13 Jul 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '16 Jul 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '20 Jul 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 03:00:44 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '23 Jul 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '27 Jul 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '30 Jul 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '03 Aug 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '06 Aug 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '10 Aug 2021 23:59' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '13 Aug 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '17 Aug 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '20 Aug 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '24 Aug 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 11:12:45

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '27 Aug 2021 00:01' | System | 20 Nov 2020 03:00:44 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '31 Aug 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '03 Sep 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '07 Sep 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '10 Sep 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '14 Sep 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '17 Sep 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '21 Sep 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '24 Sep 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '28 Sep 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '01 Oct 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '05 Oct 2021 23:59' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '08 Oct 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '12 Oct 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '15 Oct 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '19 Oct 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '22 Oct 2021 00:01' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '26 Oct 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '29 Oct 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '02 Nov 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '05 Nov 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '09 Nov 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '12 Nov 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '16 Nov 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '19 Nov 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '23 Nov 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '26 Nov 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '30 Nov 2021 23:59' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '03 Dec 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '07 Dec 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '10 Dec 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '14 Dec 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '17 Dec 2021 00:01' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '21 Dec 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '24 Dec 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '28 Dec 2021 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '31 Dec 2021 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '04 Jan 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '07 Jan 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '11 Jan 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '14 Jan 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '18 Jan 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '21 Jan 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '25 Jan 2022 23:59' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '28 Jan 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '01 Feb 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '04 Feb 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '08 Feb 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '11 Feb 2022 00:01' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '15 Feb 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '18 Feb 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '22 Feb 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '25 Feb 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '01 Mar 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '04 Mar 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '08 Mar 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '11 Mar 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '15 Mar 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '18 Mar 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '22 Mar 2022 23:59' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '25 Mar 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '29 Mar 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '01 Apr 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '05 Apr 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '08 Apr 2022 00:01' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '12 Apr 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '15 Apr 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '19 Apr 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '22 Apr 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '26 Apr 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '29 Apr 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '03 May 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '06 May 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '10 May 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '13 May 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '17 May 2022 23:59' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '20 May 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '24 May 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '27 May 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '31 May 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '03 Jun 2022 00:01' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '07 Jun 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '10 Jun 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '14 Jun 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '17 Jun 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '21 Jun 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '24 Jun 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '28 Jun 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '01 Jul 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '05 Jul 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '08 Jul 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '12 Jul 2022 23:59' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '15 Jul 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '19 Jul 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '22 Jul 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '26 Jul 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '29 Jul 2022 00:01' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '02 Aug 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '05 Aug 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '09 Aug 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '12 Aug 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '16 Aug 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '19 Aug 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '23 Aug 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '26 Aug 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '30 Aug 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '02 Sep 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '06 Sep 2022 23:59' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '09 Sep 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '13 Sep 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '16 Sep 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '20 Sep 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '23 Sep 2022 00:01' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '27 Sep 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '30 Sep 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '04 Oct 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 11:12:45

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '07 Oct 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '11 Oct 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '14 Oct 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '18 Oct 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '21 Oct 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '25 Oct 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '28 Oct 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '01 Nov 2022 23:59' | System | 20 Nov 2020 03:00:44 |



US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '04 Nov 2022 00:01' | System | 20 Nov 2020 03:00:44 |

US3732262

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:12:45**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 03:00:44 |
| Amendment Manager: User entered '08 Nov 2022 23:59' | System | 20 Nov 2020 03:00:44 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:12:45

[Date of Contact](#)

| Audit                                                          | User                  | Time (GMT)           |
|----------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)      | 23 Oct 2020 23:00:11 |
| User entered '08 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6)      | 24 Sep 2020 20:30:29 |
| User entered '10 Sep 2020' reason for change: Data Entry Error | Lauren Arnett (b) (4) | 15 Sep 2020 18:39:23 |
| User entered '08 Sep 2020' reason for change: Data Entry Error | (b) (4)               | 15 Sep 2020 18:31:53 |
| User entered '10 Sep 2020' reason for change: Data Entry Error | Lauren Arnett (b) (4) | 15 Sep 2020 18:29:50 |
| User entered '14 Sep 2020'                                     | Lauren Arnett (b) (4) | 15 Sep 2020 18:28:27 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:12:45

[Time of Contact](#)

| Audit                                                                                  | User                             | Time (GMT)           |
|----------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)                 | 23 Oct 2020 23:00:11 |
| User entered '14:01' reason for change: Data Entry Error                               | (b) (4), (b) (6)                 | 24 Sep 2020 20:30:29 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                           | 15 Sep 2020 18:40:36 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                           | 15 Sep 2020 18:40:36 |
| User entered '12:00' reason for change: Data Entry Error                               | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:40:36 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                           | 15 Sep 2020 18:39:23 |
| User entered empty; reason for change Data Entry Error                                 | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:39:23 |
| User entered '14:01' reason for change: Data Entry Error                               | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:31:53 |
| User entered '16:25'                                                                   | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:28:27 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 11:12:45**

[Date and Time of Contact \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 14:01' | System | 24 Sep 2020 20:30:29 |
| User entered '10 Sep 2020 12:00' | System | 15 Sep 2020 18:40:36 |
| User entered empty.              | System | 15 Sep 2020 18:39:23 |
| User entered '08 Sep 2020 14:01' | System | 15 Sep 2020 18:31:53 |
| User entered '10 Sep 2020 16:25' | System | 15 Sep 2020 18:29:50 |
| User entered '14 Sep 2020 16:25' | System | 15 Sep 2020 18:28:27 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 11:12:45**

[Type of Contact](#)

| Audit                                                                      | User                             | Time (GMT)           |
|----------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                        | (b) (4), (b) (6)                 | 23 Oct 2020 23:00:11 |
| User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:28:27 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 11:12:45**

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 23 Oct 2020 23:00:11 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:28:27 |



US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Symptom Day](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| User entered 'Day 2 (Day 2)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Date](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '11 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Assessment Not Done](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[O2 Saturation](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '98'   | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 11:12:45**

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Temperature](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '98.8' F | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Chills](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Cough](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Shortness of Breath](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Difficulty Breathing](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Fatigue](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Body Aches](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Headache](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Taste](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Smell](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Nasal Congestion](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Nausea](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Vomiting](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Diarrhea](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:12:45

[Sore Throat](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'Mild (Mild)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:43:04 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Symptom Day](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| User entered 'Day 3 (Day 3)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Date](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '12 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Assessment Not Done](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[O2 Saturation](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '99'   | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 26 Nov 2020 11:12:45**

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 15 Sep 2020 18:44:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Temperature](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '98.8' F | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Chills](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Cough](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Shortness of Breath](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Difficulty Breathing](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Fatigue](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Body Aches](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Headache](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Taste](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Smell](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Nasal Congestion](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Nausea](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Vomiting](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Diarrhea](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:12:45

[Sore Throat](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'Mild (Mild)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:44:25 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Symptom Day](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| User entered 'Day 4 (Day 4)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Date](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '13 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Assessment Not Done](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[O2 Saturation](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '99'   | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |



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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 26 Nov 2020 11:12:45**

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 15 Sep 2020 18:46:16 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Temperature](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '99.0' F | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Chills](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Cough](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4) | 15 Sep 2020 18:46:16 |
|                            | (b) (4)               |                      |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Difficulty Breathing](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Fatigue](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Body Aches](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Headache](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Taste](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Smell](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4) | 15 Sep 2020 18:46:16 |
|                            | (b) (4)               |                      |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Nausea](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Vomiting](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Diarrhea](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:12:45

[Sore Throat](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'Mild (Mild)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:46:16 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Symptom Day](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| User entered 'Day 5 (Day 5)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Date](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '14 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Assessment Not Done](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[O2 Saturation](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '99'   | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 26 Nov 2020 11:12:45**

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Temperature](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '99.1' F | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Chills](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Cough](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Shortness of Breath](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Difficulty Breathing](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Fatigue](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Body Aches](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Headache](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Taste](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Smell](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Nasal Congestion](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Nausea](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Vomiting](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Diarrhea](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:12:45

[Sore Throat](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered 'Mild (Mild)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 18:47:24 |



US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Symptom Day](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| User entered 'Day 6 (Day 6)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Date](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '15 Sep 2020' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Assessment Not Done](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '0'    | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[O2 Saturation](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '98' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:38:14 |
| User entered '97' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |
| User entered '97.' (non-conformant).                  | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 26 Nov 2020 11:12:45**

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '%'    | System | 22 Sep 2020 23:29:46 |
| User entered empty. | System | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Temperature](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '97.6' F | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Chills](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Cough](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Shortness of Breath](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Difficulty Breathing](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Fatigue](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Body Aches](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Headache](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Taste](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Smell](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Nasal Congestion](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Nausea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Vomiting](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Diarrhea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:12:45

[Sore Throat](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 22 Sep 2020 23:29:38 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Symptom Day](#)

| Audit                                                               | User             | Time (GMT)           |
|---------------------------------------------------------------------|------------------|----------------------|
| User entered 'Day 7 (Day 7)' reason for change:<br>Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:50 |
| User entered empty.                                                 | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Date](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 22 Sep 2020 23:37:38 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 22 Sep 2020 23:37:38 |
| User entered '16 Sep 2020' reason for change: Data Entry Error                         | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 22 Sep 2020 23:29:46 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |



US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Assessment Not Done](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '0'    | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[O2 Saturation](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '99' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                   | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 11:12:45**

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '%'    | System | 22 Sep 2020 23:37:38 |
| User entered empty. | System | 22 Sep 2020 23:29:46 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Temperature](#)

| Audit                                                     | User             | Time (GMT)           |
|-----------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '97.6' F reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                       | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Chills](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                            | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Cough](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                            | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Shortness of Breath](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                            | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Difficulty Breathing](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                            | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Fatigue](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                            | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                            | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Body Aches](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                            | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Headache](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                            | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 26 Nov 2020 11:12:45**

[New Loss of Taste](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                            | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Smell](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                            | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Nasal Congestion](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                            | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                            | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Nausea](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                            | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Vomiting](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                            | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Diarrhea](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                            | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:12:45

[Sore Throat](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:37:38 |
| User entered empty.                                            | (b) (4), (b) (6) | 22 Sep 2020 23:29:46 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 11:12:45**

[Symptom Day](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| User entered 'Day 8 (Day 8)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Date](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '17 Sep 2020' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Assessment Not Done](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '0'    | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[O2 Saturation](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '100'  | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |



US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 26 Nov 2020 11:12:45**

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Temperature](#)

| Audit                                                                                                    | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Query 'Per CDM: please review value as it seems rather high' answered with 'entry error' (Site from DM). | (b) (4), (b) (6) | 24 Nov 2020 22:53:56 |
| DataPoint Un-verified.                                                                                   | (b) (4), (b) (6) | 24 Nov 2020 22:53:51 |
| User entered '97.7' F reason for change: Data Entry Error                                                | (b) (4), (b) (6) | 24 Nov 2020 22:53:51 |
| User opened query 'Per CDM: please review value as it seems rather high' (Site from DM).                 | (b) (4), (b) (6) | 23 Nov 2020 16:12:55 |
| DataPoint Verified.                                                                                      | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '97.7' C                                                                                    | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Chills](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Cough](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Shortness of Breath](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Difficulty Breathing](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Fatigue](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Body Aches](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Headache](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Taste](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Smell](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Nasal Congestion](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Nausea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Vomiting](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Diarrhea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:12:45

[Sore Throat](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 23 Sep 2020 01:07:23 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 11:12:45**

[Symptom Day](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| User entered 'Day 9 (Day 9)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[Date](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '18 Sep 2020' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[Assessment Not Done](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '0'    | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[O2 Saturation](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '100'  | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 11:12:45**

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[Temperature](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '99.7' F | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[Chills](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[Cough](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[Shortness of Breath](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[Difficulty Breathing](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[Fatigue](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[Body Aches](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[Headache](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Taste](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Smell](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[Nasal Congestion](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 26 Nov 2020 11:12:45**

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[Nausea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[Vomiting](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[Diarrhea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:12:45

[Sore Throat](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 23 Sep 2020 01:13:56 |



US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 11:12:45**

[Symptom Day](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| User entered 'Day 10 (Day 10)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[Date](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '19 Sep 2020' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[Assessment Not Done](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '0'    | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[O2 Saturation](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '99'   | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 11:12:45**

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[Temperature](#)

| Audit                                                                                                    | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Query 'Per CDM: please review value as it seems rather high' answered with 'entry error' (Site from DM). | (b) (4), (b) (6) | 24 Nov 2020 22:54:28 |
| DataPoint Un-verified.                                                                                   | (b) (4), (b) (6) | 24 Nov 2020 22:54:19 |
| User entered '98.4' F reason for change: Data Entry Error                                                | (b) (4), (b) (6) | 24 Nov 2020 22:54:19 |
| User opened query 'Per CDM: please review value as it seems rather high' (Site from DM).                 | (b) (4), (b) (6) | 23 Nov 2020 16:13:10 |
| DataPoint Verified.                                                                                      | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '98.4' C                                                                                    | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[Chills](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[Cough](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[Shortness of Breath](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[Difficulty Breathing](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[Fatigue](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[Body Aches](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[Headache](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Taste](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Smell](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |



US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 11:12:45**

[Nasal Congestion](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[Nausea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[Vomiting](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[Diarrhea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:12:45

[Sore Throat](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:15:05 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Symptom Day](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| User entered 'Day 12 (Day 12)' | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Date](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '21 Sep 2020' | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Assessment Not Done](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '0'    | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[O2 Saturation](#)

| Audit                                                                                                                    | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                      | (b) (4), (b) (6) | 06 Nov 2020 22:49:04 |
| User closed query 'Per Source; "O2 Saturation = 99%". Please update data point.' (Site from CRA).                        | (b) (4), (b) (6) | 06 Nov 2020 22:48:57 |
| Query 'Per Source; "O2 Saturation = 99%". Please update data point.' answered with 'updated per source' (Site from CRA). | (b) (4), (b) (6) | 05 Nov 2020 19:16:29 |
| DataPoint Un-verified.                                                                                                   | (b) (4), (b) (6) | 05 Nov 2020 19:16:20 |
| User entered '99' reason for change: Data Entry Error                                                                    | (b) (4), (b) (6) | 05 Nov 2020 19:16:20 |
| DataPoint Verified.                                                                                                      | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User opened query 'Per Source; "O2 Saturation = 99%". Please update data point.' (Site from CRA).                        | (b) (4), (b) (6) | 23 Oct 2020 23:10:31 |
| User entered empty.                                                                                                      | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 11:12:45**

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '%'    | System | 05 Nov 2020 19:16:20 |
| User entered empty. | System | 23 Sep 2020 01:16:22 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Temperature](#)

| Audit                                                                                                                      | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                        | (b) (4), (b) (6) | 06 Nov 2020 22:49:05 |
| User closed query 'Per Source, " Temperature = 97.5 F". Please update data point.' (Site from CRA).                        | (b) (4), (b) (6) | 06 Nov 2020 22:49:01 |
| Query 'Per Source, " Temperature = 97.5 F". Please update data point.' answered with 'updated per source' (Site from CRA). | (b) (4), (b) (6) | 05 Nov 2020 19:16:41 |
| DataPoint Un-verified.                                                                                                     | (b) (4), (b) (6) | 05 Nov 2020 19:16:20 |
| User entered '97.5' F reason for change: Data Entry Error                                                                  | (b) (4), (b) (6) | 05 Nov 2020 19:16:20 |
| DataPoint Verified.                                                                                                        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User opened query 'Per Source, " Temperature = 97.5 F". Please update data point.' (Site from CRA).                        | (b) (4), (b) (6) | 23 Oct 2020 23:11:04 |
| User entered empty.                                                                                                        | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Chills](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Cough](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Shortness of Breath](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Difficulty Breathing](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Fatigue](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |
| User entered 'Mild (Mild)'                                     | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Body Aches](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Headache](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Taste](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Smell](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Nasal Congestion](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Nausea](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |
| User entered 'Mild (Mild)'                                     | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Vomiting](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Diarrhea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:12:45

[Sore Throat](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:16:22 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Symptom Day](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| User entered 'Day 13 (Day 13)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Date](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '22 Sep 2020' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Assessment Not Done](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '0'    | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[O2 Saturation](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '99'   | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |



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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 11:12:45**

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Temperature](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '97.2' F | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Chills](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Cough](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Shortness of Breath](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Difficulty Breathing](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Fatigue](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Body Aches](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Headache](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Taste](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Smell](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 11:12:45**

[Nasal Congestion](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Nausea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Vomiting](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Diarrhea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:12:45

[Sore Throat](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 23 Sep 2020 01:17:25 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 11:12:45**

[Symptom Day](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| User entered 'Day 14 (Day 14)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |
|                                |                  |                      |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Date](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '23 Sep 2020' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Assessment Not Done](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '0'    | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[O2 Saturation](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '99'   | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 11:12:45**

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Temperature](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '97.7' F | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Chills](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Cough](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Shortness of Breath](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Difficulty Breathing](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Fatigue](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Body Aches](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Headache](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Taste](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Smell](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Nasal Congestion](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Nausea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Vomiting](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Diarrhea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:12:45

[Sore Throat](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 19:57:45 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Symptom Day](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| User entered 'Day 21 (Day 21)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |
|                                |                  |                      |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Date](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '30 Sep 2020' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Assessment Not Done](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '0'    | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[O2 Saturation](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '99'   | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 11:12:45**

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 30 Sep 2020 20:01:33 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Temperature](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '99.1' F | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Chills](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Cough](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Shortness of Breath](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Difficulty Breathing](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Fatigue](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Body Aches](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Headache](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Taste](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (14)**

**Generated On: 26 Nov 2020 11:12:45**

[New Loss of Smell](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |



US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Nasal Congestion](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Nausea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Vomiting](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Diarrhea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:12:45

[Sore Throat](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Sep 2020 20:01:33 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 11:12:45**

[Symptom Day](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| User entered 'Day 1 (Day 1)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Date](#)

| Audit                                                                                                                                                                                                                                                                                                                                      | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User closed query 'Per CDM; Please reconcile Day 1 date as it appears to be after Contact date of 08SEP2020' (Site from DM).                                                                                                                                                                                                               | (b) (4), (b) (6)                 | 10 Nov 2020 20:10:21 |
| Query 'Per CDM; Please reconcile Day 1 date as it appears to be after Contact date of 08SEP2020' answered with 'data entered is correct as is, please note that subject was positive at baseline visit, site received +PCR results and contacted subject on 9/8, subject returned to site for day 1 illness visit om 9/10' (Site from DM). | Lauren Arnett (b) (4)<br>(b) (4) | 09 Nov 2020 17:05:38 |
| User opened query 'Per CDM; Please reconcile Day 1 date as it appears to be after Contact date of 08SEP2020' (Site from DM).                                                                                                                                                                                                               | (b) (4), (b) (6)                 | 09 Nov 2020 06:03:05 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)                 | 23 Oct 2020 23:12:58 |
| User entered '10 Sep 2020'                                                                                                                                                                                                                                                                                                                 | (b) (4), (b) (6)                 | 07 Oct 2020 20:16:04 |



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Assessment Not Done](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '0'    | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[O2 Saturation](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '98'   | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (15)**

**Generated On: 26 Nov 2020 11:12:45**

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 07 Oct 2020 20:16:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Temperature](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered '100.0' F | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Chills](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Cough](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Shortness of Breath](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Difficulty Breathing](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Fatigue](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Body Aches](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Headache](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Taste](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[New Loss of Smell](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Nasal Congestion](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Nausea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Vomiting](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Diarrhea](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'None (None)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:12:45

[Sore Throat](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:12:58 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 07 Oct 2020 20:16:04 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:12:45

[Date of Visit](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:13:42 |
| User entered '10 Sep 2020' | (b) (4), (b) (6) | 22 Sep 2020 23:27:45 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 11:12:45**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 23 Oct 2020 23:13:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 23:27:45 |

US3732262

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:12:45

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit                                                                                                                                                                                                                      | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).                        | (b) (4), (b) (6) | 06 Nov 2020 04:05:13 |
| Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'previously updated' (Site from System). | (b) (4), (b) (6) | 05 Nov 2020 19:09:26 |
| DataPoint Verified.                                                                                                                                                                                                        | (b) (4), (b) (6) | 23 Oct 2020 23:13:42 |
| User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).                        | System           | 22 Sep 2020 23:27:45 |
| User entered 'Yes (Y)'                                                                                                                                                                                                     | (b) (4), (b) (6) | 22 Sep 2020 23:27:45 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:12:45

[Date of Test](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:13:42 |
| User entered '10 Sep 2020' | (b) (4), (b) (6) | 22 Sep 2020 23:27:45 |



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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 11:12:45**

[Type of Test Performed](#)

| Audit                                                    | User             | Time (GMT)           |
|----------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6) | 23 Oct 2020 23:13:42 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | (b) (4), (b) (6) | 22 Sep 2020 23:27:45 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:12:45

[Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:13:42 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 23:27:45 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:12:45

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 23 Oct 2020 23:13:42 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 23:27:45 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 11:12:45**

[Lab/ Institution Test Performed](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:13:42 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 23:27:45 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 11:12:45**

[CLIA Certified?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:13:42 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 23:27:45 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 11:12:45**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Sep 2020 23:27:45 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Did the subject have Respiratory Rates  \$\geq\$  30 per Minute?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered 'No (N)' | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Start Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |



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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[End Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

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**Generated On: 26 Nov 2020 11:12:45**

[Respiratory Rate](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Did the subject have Heart Rate  \$\geq\$  125 beats per minute](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered 'No (N)' | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Start Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[End Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

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[Heart Rate](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

Did the subject have Oxygen Saturation of  $\text{SpO}_2 \leq 93\%$  on room air at sea level?

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered 'No (N)' | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Start Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |



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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[End Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:12:45

[Oxygen Saturation](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered 'No (N)' | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Start Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[End Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[PaO2](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Did the subject have Respiratory failure?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered 'No (N)' | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Start Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |



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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered 'No (N)' | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Start Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[High-Flow Oxygen?](#)

| Audit                                                     | User             | Time (GMT)           |
|-----------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 15 Oct 2020 00:37:39 |
| User entered empty.                                       | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Start Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[End Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Non-Invasive Ventilation?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Start Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[End Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |



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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Mechanical Ventilation?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Start Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[End Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[ECMO?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Start Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[End Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

| Audit                                                     | User             | Time (GMT)           |
|-----------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 15 Oct 2020 00:37:39 |
| User entered empty.                                       | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Start Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |



US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[End Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Evidence of Shock Requires  
Vasopressors](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Start Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[End Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Acute Renal Dysfunction?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Start Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Hepatic Dysfunction?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Start Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |



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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Neurologic Dysfunction?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Start Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Clinical Evidence](#)

| Audit                                                     | User             | Time (GMT)           |
|-----------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 15 Oct 2020 00:37:39 |
| User entered empty.                                       | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Date of Assessment](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Radiographical Evidence](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Date of Assessment](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Admission to an intensive care unit due to SARS-CoV-2](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 07 Oct 2020 20:17:34 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 07 Oct 2020 20:17:34 |
| User entered 'No (N)' reason for change: Data Entry Error                              | (b) (4), (b) (6) | 07 Oct 2020 20:17:34 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 07 Oct 2020 20:17:22 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

US3732262

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Start Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |



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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[End Date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:14:24 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 20:17:22 |

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Generate Next COVID-19 Assessment](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 10 Nov 2020 18:24:05 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 09 Nov 2020 18:23:58 |

US3732262

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Visit](#)

| Audit                                       | User             | Time (GMT)           |
|---------------------------------------------|------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

US3732262

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Was Saliva Collected?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:53:44 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Date of Collection](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 06 Nov 2020 22:53:45 |
| User entered '12 Sep 2020' | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

US3732262

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Visit](#)

| Audit                                       | User             | Time (GMT)           |
|---------------------------------------------|------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Was Saliva Collected?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:58:12 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

US3732262

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Date of Collection](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 06 Nov 2020 22:58:12 |
| User entered '14 Sep 2020' | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |



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**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Visit](#)

| Audit                                       | User             | Time (GMT)           |
|---------------------------------------------|------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Was Saliva Collected?](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 06 Nov 2020 22:58:12 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 13 Oct 2020 22:04:06 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 13 Oct 2020 22:04:06 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | (b) (4), (b) (6) | 13 Oct 2020 22:04:06 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 23 Sep 2020 01:04:29 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Date of Collection](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 06 Nov 2020 22:58:12 |
| User entered '16 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Oct 2020 22:04:06 |
| User entered empty.                                            | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

US3732262

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Visit](#)

| Audit                                       | User             | Time (GMT)           |
|---------------------------------------------|------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

US3732262

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Was Saliva Collected?](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 06 Nov 2020 22:58:12 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 13 Oct 2020 22:05:53 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 13 Oct 2020 22:05:53 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | (b) (4), (b) (6) | 13 Oct 2020 22:05:53 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 23 Sep 2020 01:04:29 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Date of Collection](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 06 Nov 2020 22:58:12 |
| User entered '18 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Oct 2020 22:05:53 |
| User entered empty.                                            | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Visit](#)

| Audit                                         | User             | Time (GMT)           |
|-----------------------------------------------|------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Was Saliva Collected?](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 06 Nov 2020 22:58:12 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 13 Oct 2020 22:05:53 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 13 Oct 2020 22:05:53 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | (b) (4), (b) (6) | 13 Oct 2020 22:05:53 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 23 Sep 2020 01:04:29 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |



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**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Date of Collection](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 06 Nov 2020 22:58:12 |
| User entered '23 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Oct 2020 22:05:53 |
| User entered empty.                                            | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

US3732262

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Visit](#)

| Audit                                         | User             | Time (GMT)           |
|-----------------------------------------------|------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Was Saliva Collected?](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 06 Nov 2020 22:58:12 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 13 Oct 2020 22:05:53 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 13 Oct 2020 22:05:53 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | (b) (4), (b) (6) | 13 Oct 2020 22:05:53 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 23 Sep 2020 01:04:29 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Date of Collection](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 06 Nov 2020 22:58:12 |
| User entered '30 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Oct 2020 22:05:53 |
| User entered empty.                                            | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Visit](#)

| Audit                                         | User             | Time (GMT)           |
|-----------------------------------------------|------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Was Saliva Collected?](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 06 Nov 2020 22:58:12 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 13 Oct 2020 22:05:53 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 13 Oct 2020 22:05:53 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | (b) (4), (b) (6) | 13 Oct 2020 22:05:53 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 23 Sep 2020 01:04:29 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 23 Sep 2020 01:04:29 |

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:12:45

[Date of Collection](#)

| Audit                                                          | User                  | Time (GMT)           |
|----------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Un-verified.                                         | Lauren Arnett (b) (4) | 18 Nov 2020 22:19:24 |
|                                                                | (b) (4)               |                      |
| User entered '07 Oct 2020' reason for change: Data Entry Error | Lauren Arnett (b) (4) | 18 Nov 2020 22:19:24 |
|                                                                | (b) (4)               |                      |
| DataPoint Verified.                                            | (b) (4), (b) (6)      | 06 Nov 2020 22:58:12 |
|                                                                | (b) (4), (b) (6)      |                      |
| User entered '7 Oct 2020' reason for change: Data Entry Error  | (b) (4), (b) (6)      | 13 Oct 2020 22:05:53 |
|                                                                |                       |                      |
| User entered empty.                                            | (b) (4), (b) (6)      | 23 Sep 2020 01:04:29 |
|                                                                |                       |                      |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

[Was this visit performed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 23 Oct 2020 23:15:24 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 23:54:25 |



US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:15:24 |
| User entered '10 Sep 2020' | (b) (4), (b) (6) | 22 Sep 2020 23:54:25 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 23 Oct 2020 23:15:24 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 22 Sep 2020 23:54:25 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'SICKD1' | System | 22 Sep 2020 23:54:25 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Were vital signs assessed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 23 Oct 2020 23:15:53 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 23 Sep 2020 01:05:27 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:15:53 |
| User entered '10 Sep 2020' | (b) (4), (b) (6) | 23 Sep 2020 01:05:27 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 23 Oct 2020 23:15:53 |
| User entered '12:15' | (b) (4), (b) (6) | 23 Sep 2020 01:05:27 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Sep 2020 12:15' | System | 23 Sep 2020 01:05:27 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Height \(xxx.x\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 23 Oct 2020 23:15:53 |
| User entered '161.6' cm   | (b) (4), (b) (6) | 23 Sep 2020 01:05:27 |
| DataPoint set to visible. | System           | 22 Sep 2020 23:54:25 |



US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

Weight (xxx.x)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 23 Oct 2020 23:15:53 |
| User entered '81.0' kg    | (b) (4), (b) (6) | 23 Sep 2020 01:05:27 |
| DataPoint set to visible. | System           | 22 Sep 2020 23:54:25 |

US3732262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

Temperature (xxx.x)

| Audit                                                                                   | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                     | (b) (4), (b) (6) | 23 Oct 2020 23:15:53 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System           | 23 Sep 2020 01:05:33 |
| User entered '100.0' F reason for change: Data Entry Error                              | (b) (4), (b) (6) | 23 Sep 2020 01:05:33 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System           | 23 Sep 2020 01:05:27 |
| User entered '100.0' (non-conformant).                                                  | (b) (4), (b) (6) | 23 Sep 2020 01:05:27 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Route of measurement](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:15:53 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 23 Sep 2020 01:05:27 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[If Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:15:53 |
| User entered empty. | (b) (4), (b) (6) | 23 Sep 2020 01:05:27 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Pulse \(xxx\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:15:53 |
| User entered '73'   | (b) (4), (b) (6) | 23 Sep 2020 01:05:27 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 23 Sep 2020 01:05:27 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Respiratory Rate \(xxx\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:15:53 |
| User entered '16'   | (b) (4), (b) (6) | 23 Sep 2020 01:05:27 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 23 Sep 2020 01:05:27 |



US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Systolic Blood Pressure \(xxx\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:15:53 |
| User entered '143'  | (b) (4), (b) (6) | 23 Sep 2020 01:05:27 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 23 Sep 2020 01:05:27 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:15:53 |
| User entered '89'   | (b) (4), (b) (6) | 23 Sep 2020 01:05:27 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 23 Sep 2020 01:05:27 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 11:12:45**

[Was the physical examination performed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 23 Oct 2020 23:16:09 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 23 Sep 2020 01:05:45 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 11:12:45**

[Date of examination \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:16:09 |
| User entered '10 Sep 2020' | (b) (4), (b) (6) | 23 Sep 2020 01:05:45 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 26 Nov 2020 11:12:45**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 23 Oct 2020 23:16:18 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 23 Sep 2020 01:05:54 |

US3732262

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 26 Nov 2020 11:12:45**

[Date of Collection](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:16:18 |
| User entered '10 Sep 2020' | (b) (4), (b) (6) | 23 Sep 2020 01:05:54 |



US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

[Was this visit performed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 23 Oct 2020 23:17:07 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Oct 2020 16:51:45 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

[Visit date \(dd MMM yyyy\)](#)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 10 Nov 2020 18:25:16 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6) | 10 Nov 2020 17:57:43 |
| User entered '07 Oct 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 10 Nov 2020 17:57:43 |
| DataPoint Verified.                                            | (b) (4), (b) (6) | 23 Oct 2020 23:17:07 |
| User entered '7 Oct 2020'                                      | (b) (4), (b) (6) | 08 Oct 2020 16:51:45 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 23 Oct 2020 23:17:07 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 08 Oct 2020 16:51:45 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:12:45**

[Folder OID](#)

| Audit                  | User   | Time (GMT)           |
|------------------------|--------|----------------------|
| User entered 'SICKD28' | System | 08 Oct 2020 16:51:45 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Were vital signs assessed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 23 Oct 2020 23:17:41 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Oct 2020 22:01:42 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                                                          | User                  | Time (GMT)           |
|----------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Un-verified.                                         | Lauren Arnett (b) (4) | 18 Nov 2020 22:19:10 |
|                                                                | (b) (4)               |                      |
| User entered '07 Oct 2020' reason for change: Data Entry Error | Lauren Arnett (b) (4) | 18 Nov 2020 22:19:10 |
|                                                                | (b) (4)               |                      |
| DataPoint Verified.                                            | (b) (4), (b) (6)      | 23 Oct 2020 23:17:41 |
|                                                                |                       |                      |
| User entered '7 Oct 2020'                                      | (b) (4), (b) (6)      | 13 Oct 2020 22:01:42 |
|                                                                |                       |                      |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 23 Oct 2020 23:17:41 |
| User entered '14:05' | (b) (4), (b) (6) | 13 Oct 2020 22:01:42 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 14:05' | System | 18 Nov 2020 22:19:10 |
| User entered '7 Oct 2020 14:05'  | System | 13 Oct 2020 22:01:42 |



US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

[Height \(xxx.x\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 23 Oct 2020 23:17:41 |
| User entered '162.3' cm   | (b) (4), (b) (6) | 13 Oct 2020 22:01:42 |
| DataPoint set to visible. | System           | 08 Oct 2020 16:51:45 |

US3732262

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

[Weight \(xxx.x\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 23 Oct 2020 23:17:41 |
| User entered '080.3' kg   | (b) (4), (b) (6) | 13 Oct 2020 22:01:42 |
| DataPoint set to visible. | System           | 08 Oct 2020 16:51:45 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Temperature \(xxx.x\)](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 23 Oct 2020 23:17:41 |
| User entered '98.6' F | (b) (4), (b) (6) | 13 Oct 2020 22:01:42 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Route of measurement](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 23 Oct 2020 23:17:41 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 13 Oct 2020 22:01:42 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[If Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:17:41 |
| User entered empty. | (b) (4), (b) (6) | 13 Oct 2020 22:01:42 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Pulse \(xxx\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:17:41 |
| User entered '92'   | (b) (4), (b) (6) | 13 Oct 2020 22:01:42 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 13 Oct 2020 22:01:42 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Respiratory Rate \(xxx\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:17:41 |
| User entered '14'   | (b) (4), (b) (6) | 13 Oct 2020 22:01:42 |



US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 13 Oct 2020 22:01:42 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Systolic Blood Pressure \(xxx\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:17:41 |
| User entered '119'  | (b) (4), (b) (6) | 13 Oct 2020 22:01:42 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 13 Oct 2020 22:01:42 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 23 Oct 2020 23:17:41 |
| User entered '70'   | (b) (4), (b) (6) | 13 Oct 2020 22:01:42 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 13 Oct 2020 22:01:42 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 11:12:45**

[Was the physical examination performed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 23 Oct 2020 23:18:07 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Oct 2020 22:01:56 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 11:12:45**

**Date of examination (dd MMM yyyy)**

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6) | 23 Oct 2020 23:18:07 |
| User entered '7 Oct 2020' | (b) (4), (b) (6) | 13 Oct 2020 22:01:56 |

US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 26 Nov 2020 11:12:45**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 23 Oct 2020 23:18:18 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Oct 2020 22:02:12 |



US3732262

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 26 Nov 2020 11:12:45**

[Date of Collection](#)

| Audit                                                          | User                  | Time (GMT)           |
|----------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Un-verified.                                         | Lauren Arnett (b) (4) | 18 Nov 2020 22:19:16 |
|                                                                | (b) (4)               |                      |
| User entered '07 Oct 2020' reason for change: Data Entry Error | Lauren Arnett (b) (4) | 18 Nov 2020 22:19:16 |
|                                                                | (b) (4)               |                      |
| DataPoint Verified.                                            | (b) (4), (b) (6)      | 23 Oct 2020 23:18:18 |
|                                                                |                       |                      |
| User entered '7 Oct 2020'                                      | (b) (4), (b) (6)      | 13 Oct 2020 22:02:12 |
|                                                                |                       |                      |

US3732262

Folder: Unscheduled 10 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 11:12:45

[Visit Date](#)

| Audit                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                                      | (b) (4), (b) (6) | 09 Nov 2020 20:55:04 |
| User closed query 'Per CDM: Please consider removing all data from this visit permitting inactivation of forms as it appears to be a duplicate of Illness Visit day 1' (Site from DM).                                          | (b) (4), (b) (6) | 09 Nov 2020 20:55:02 |
| Query 'Data is required. Please complete.' answered with 'Created in error' (Site from System).                                                                                                                                 | (b) (4), (b) (6) | 09 Nov 2020 19:57:05 |
| Query 'Per CDM: Please consider removing all data from this visit permitting inactivation of forms as it appears to be a duplicate of Illness Visit day 1' answered with 'updated. per updated eCRF Guidelines' (Site from DM). | (b) (4), (b) (6) | 09 Nov 2020 19:57:02 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                                                                      | System           | 09 Nov 2020 19:56:40 |
| DataPoint Un-verified.                                                                                                                                                                                                          | (b) (4), (b) (6) | 09 Nov 2020 19:56:40 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                                          | (b) (4), (b) (6) | 09 Nov 2020 19:56:40 |
| User opened query 'Per CDM: Please consider removing all data from this visit permitting inactivation of forms as it appears to be a duplicate of Illness Visit day 1' (Site from DM).                                          | (b) (4), (b) (6) | 09 Nov 2020 06:00:59 |
| DataPoint Verified.                                                                                                                                                                                                             | (b) (4), (b) (6) | 06 Nov 2020 22:58:25 |
| User entered '10 Sep 2020'                                                                                                                                                                                                      | (b) (4), (b) (6) | 15 Oct 2020 00:38:52 |

US3732262

**Folder: Unscheduled 10 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Physical Exam](#)

| Audit                                                | User             | Time (GMT)           |
|------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                               | (b) (4), (b) (6) | 09 Nov 2020 19:56:40 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:56:40 |
| DataPoint Verified.                                  | (b) (4), (b) (6) | 06 Nov 2020 22:58:25 |
| User entered '1'                                     | (b) (4), (b) (6) | 15 Oct 2020 00:38:52 |

US3732262

**Folder: Unscheduled 10 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Vital Signs](#)

| Audit                                                | User             | Time (GMT)           |
|------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                               | (b) (4), (b) (6) | 09 Nov 2020 19:56:40 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:56:40 |
| DataPoint Verified.                                  | (b) (4), (b) (6) | 06 Nov 2020 22:58:25 |
| User entered '1'                                     | (b) (4), (b) (6) | 15 Oct 2020 00:38:52 |

US3732262

**Folder: Unscheduled 10 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Immunogenicity Assessment](#)

| Audit                                                | User             | Time (GMT)           |
|------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                               | (b) (4), (b) (6) | 09 Nov 2020 19:56:40 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:56:40 |
| DataPoint Verified.                                  | (b) (4), (b) (6) | 06 Nov 2020 22:58:25 |
| User entered '1'                                     | (b) (4), (b) (6) | 15 Oct 2020 00:38:52 |

US3732262

**Folder: Unscheduled 10 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Pregnancy Test](#)

| Audit                                                | User             | Time (GMT)           |
|------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                               | (b) (4), (b) (6) | 09 Nov 2020 19:56:40 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:56:40 |
| DataPoint Verified.                                  | (b) (4), (b) (6) | 06 Nov 2020 22:58:25 |
| User entered '1'                                     | (b) (4), (b) (6) | 15 Oct 2020 00:38:52 |

US3732262

Folder: Unscheduled 10 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

[Were vital signs assessed?](#)

| Audit                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).                      | (b) (4), (b) (6) | 09 Nov 2020 20:54:51 |
| Query 'Data is required. Please complete.' answered with 'Created in error' (Site from System). | (b) (4), (b) (6) | 09 Nov 2020 19:57:36 |
| User opened query 'Data is required. Please complete.' (Site from System).                      | System           | 09 Nov 2020 19:57:32 |
| DataPoint Un-verified.                                                                          | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| User entered empty; reason for change Data Entry Error                                          | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| DataPoint Verified.                                                                             | (b) (4), (b) (6) | 06 Nov 2020 22:58:45 |
| User entered 'Yes (Y)'                                                                          | (b) (4), (b) (6) | 15 Oct 2020 00:39:22 |

US3732262

**Folder: Unscheduled 10 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                                 | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| DataPoint Verified.                                    | (b) (4), (b) (6) | 06 Nov 2020 22:58:45 |
| User entered '10 Sep 2020'                             | (b) (4), (b) (6) | 15 Oct 2020 00:39:22 |



US3732262

**Folder: Unscheduled 10 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Time of assessment \(00:00-23:59\)](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                                 | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| DataPoint Verified.                                    | (b) (4), (b) (6) | 06 Nov 2020 22:58:45 |
| User entered '12:15'                                   | (b) (4), (b) (6) | 15 Oct 2020 00:39:22 |

US3732262

**Folder: Unscheduled 10 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered empty.              | System | 09 Nov 2020 19:57:32 |
| User entered '10 Sep 2020 12:15' | System | 15 Oct 2020 00:39:22 |

US3732262

Folder: Unscheduled 10 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

Temperature (xxx.x)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                                 | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| DataPoint Verified.                                    | (b) (4), (b) (6) | 06 Nov 2020 22:58:45 |
| User entered '100.0' F                                 | (b) (4), (b) (6) | 15 Oct 2020 00:39:22 |

US3732262

**Folder: Unscheduled 10 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Route of measurement](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                                 | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| DataPoint Verified.                                    | (b) (4), (b) (6) | 06 Nov 2020 22:58:45 |
| User entered 'Oral (Oral)'                             | (b) (4), (b) (6) | 15 Oct 2020 00:39:22 |

US3732262

**Folder:** Unscheduled 10 Sep 2020

**Form:** Vital Signs

**Generated On:** 26 Nov 2020 11:12:45

[If Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 22:58:45 |
| User entered empty. | (b) (4), (b) (6) | 15 Oct 2020 00:39:22 |

US3732262

Folder: Unscheduled 10 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

[Pulse \(xxx\)](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                                 | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| DataPoint Verified.                                    | (b) (4), (b) (6) | 06 Nov 2020 22:58:45 |
| User entered '73'                                      | (b) (4), (b) (6) | 15 Oct 2020 00:39:22 |

US3732262

**Folder:** Unscheduled 10 Sep 2020

**Form:** Vital Signs

**Generated On:** 26 Nov 2020 11:12:45

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Nov 2020 19:57:32 |
| User entered 'bpm'  | System | 15 Oct 2020 00:39:22 |

US3732262

Folder: Unscheduled 10 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

[Respiratory Rate \(xxx\)](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                                 | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| DataPoint Verified.                                    | (b) (4), (b) (6) | 06 Nov 2020 22:58:45 |
| User entered '16'                                      | (b) (4), (b) (6) | 15 Oct 2020 00:39:22 |



US3732262

**Folder: Unscheduled 10 Sep 2020**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:12:45**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered empty.        | System | 09 Nov 2020 19:57:32 |
| User entered 'breaths/min' | System | 15 Oct 2020 00:39:22 |

US3732262

Folder: Unscheduled 10 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

[Systolic Blood Pressure \(xxx\)](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                                 | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| DataPoint Verified.                                    | (b) (4), (b) (6) | 06 Nov 2020 22:58:45 |
| User entered '143'                                     | (b) (4), (b) (6) | 15 Oct 2020 00:39:22 |

US3732262

**Folder:** Unscheduled 10 Sep 2020

**Form:** Vital Signs

**Generated On:** 26 Nov 2020 11:12:45

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Nov 2020 19:57:32 |
| User entered 'mmHg' | System | 15 Oct 2020 00:39:22 |

US3732262

Folder: Unscheduled 10 Sep 2020

Form: Vital Signs

Generated On: 26 Nov 2020 11:12:45

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                                 | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:57:32 |
| DataPoint Verified.                                    | (b) (4), (b) (6) | 06 Nov 2020 22:58:45 |
| User entered '89'                                      | (b) (4), (b) (6) | 15 Oct 2020 00:39:22 |

US3732262

**Folder:** Unscheduled 10 Sep 2020

**Form:** Vital Signs

**Generated On:** 26 Nov 2020 11:12:45

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Nov 2020 19:57:32 |
| User entered 'mmHg' | System | 15 Oct 2020 00:39:22 |

US3732262

Folder: Unscheduled 10 Sep 2020

Form: Physical Examination

Generated On: 26 Nov 2020 11:12:45

[Was the physical examination performed?](#)

| Audit                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).                      | (b) (4), (b) (6) | 09 Nov 2020 20:55:08 |
| Query 'Data is required. Please complete.' answered with 'Created in error' (Site from System). | (b) (4), (b) (6) | 09 Nov 2020 19:59:35 |
| User opened query 'Data is required. Please complete.' (Site from System).                      | System           | 09 Nov 2020 19:59:28 |
| DataPoint Un-verified.                                                                          | (b) (4), (b) (6) | 09 Nov 2020 19:59:28 |
| User entered empty; reason for change Data Entry Error                                          | (b) (4), (b) (6) | 09 Nov 2020 19:59:28 |
| DataPoint Verified.                                                                             | (b) (4), (b) (6) | 06 Nov 2020 22:58:53 |
| User entered 'Yes (Y)'                                                                          | (b) (4), (b) (6) | 15 Oct 2020 00:39:32 |

US3732262

**Folder: Unscheduled 10 Sep 2020**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 11:12:45**

[Date of examination \(dd MMM yyyy\)](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                                 | (b) (4), (b) (6) | 09 Nov 2020 19:59:28 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:59:28 |
| DataPoint Verified.                                    | (b) (4), (b) (6) | 06 Nov 2020 22:58:53 |
| User entered '10 Sep 2020'                             | (b) (4), (b) (6) | 15 Oct 2020 00:39:32 |

US3732262

Folder: Unscheduled 10 Sep 2020

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:12:45

[Was the pregnancy test performed?](#)

| Audit                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).                      | (b) (4), (b) (6) | 09 Nov 2020 20:55:11 |
| Query 'Data is required. Please complete.' answered with 'Created in error' (Site from System). | (b) (4), (b) (6) | 09 Nov 2020 19:59:57 |
| User opened query 'Data is required. Please complete.' (Site from System).                      | System           | 09 Nov 2020 19:59:52 |
| DataPoint Un-verified.                                                                          | (b) (4), (b) (6) | 09 Nov 2020 19:59:52 |
| User entered empty; reason for change Data Entry Error                                          | (b) (4), (b) (6) | 09 Nov 2020 19:59:52 |
| DataPoint Verified.                                                                             | (b) (4), (b) (6) | 06 Nov 2020 22:59:07 |
| User entered 'Yes (Y)'                                                                          | (b) (4), (b) (6) | 15 Oct 2020 00:39:55 |



US3732262

**Folder: Unscheduled 10 Sep 2020**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 11:12:45**

[Date of test \(dd MMM yyyy\)](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                                 | (b) (4), (b) (6) | 09 Nov 2020 19:59:52 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:59:52 |
| DataPoint Verified.                                    | (b) (4), (b) (6) | 06 Nov 2020 22:59:07 |
| User entered '10 Sep 2020'                             | (b) (4), (b) (6) | 15 Oct 2020 00:39:55 |

US3732262

**Folder:** Unscheduled 10 Sep 2020

**Form:** Pregnancy Test

**Generated On:** 26 Nov 2020 11:12:45

[Test performed](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                                 | (b) (4), (b) (6) | 09 Nov 2020 19:59:52 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:59:52 |
| DataPoint Verified.                                    | (b) (4), (b) (6) | 06 Nov 2020 22:59:07 |
| User entered 'Serum (SERUM)'                           | (b) (4), (b) (6) | 15 Oct 2020 00:39:55 |

US3732262

**Folder: Unscheduled 10 Sep 2020**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 11:12:45**

[Result](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                                 | (b) (4), (b) (6) | 09 Nov 2020 19:59:52 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:59:52 |
| DataPoint Verified.                                    | (b) (4), (b) (6) | 06 Nov 2020 22:59:07 |
| User entered 'Negative (NEGATIVE)'                     | (b) (4), (b) (6) | 15 Oct 2020 00:39:55 |

US3732262

**Folder: Unscheduled 10 Sep 2020**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 11:12:45**

[Was FSH sample collected?](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                                 | (b) (4), (b) (6) | 09 Nov 2020 19:59:52 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 19:59:52 |
| DataPoint Verified.                                    | (b) (4), (b) (6) | 06 Nov 2020 22:59:07 |
| User entered 'No (N)'                                  | (b) (4), (b) (6) | 15 Oct 2020 00:39:55 |

US3732262

Folder: Unscheduled 10 Sep 2020

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:12:45

[Collection date](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 22:59:07 |
| User entered empty. | (b) (4), (b) (6) | 15 Oct 2020 00:39:55 |

US3732262

**Folder:** Unscheduled 10 Sep 2020

**Form:** Pregnancy Test

**Generated On:** 26 Nov 2020 11:12:45

[Collection time](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 22:59:07 |
| User entered empty. | (b) (4), (b) (6) | 15 Oct 2020 00:39:55 |

US3732262

**Folder: Unscheduled 10 Sep 2020**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 11:12:45**

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 15 Oct 2020 00:39:55 |

US3732262

Folder: Unscheduled 10 Sep 2020

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:12:45

[Was the sample collected?](#)

| Audit                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).                      | (b) (4), (b) (6) | 09 Nov 2020 20:55:14 |
| Query 'Data is required. Please complete.' answered with 'Created in error' (Site from System). | (b) (4), (b) (6) | 09 Nov 2020 20:00:35 |
| User opened query 'Data is required. Please complete.' (Site from System).                      | System           | 09 Nov 2020 20:00:17 |
| DataPoint Un-verified.                                                                          | (b) (4), (b) (6) | 09 Nov 2020 20:00:17 |
| User entered empty; reason for change Data Entry Error                                          | (b) (4), (b) (6) | 09 Nov 2020 20:00:17 |
| DataPoint Verified.                                                                             | (b) (4), (b) (6) | 06 Nov 2020 22:59:15 |
| User entered 'Yes (Y)'                                                                          | (b) (4), (b) (6) | 15 Oct 2020 00:40:07 |



US3732262

**Folder: Unscheduled 10 Sep 2020**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Collection date \(dd MMM yyyy\)](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                                 | (b) (4), (b) (6) | 09 Nov 2020 20:00:17 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 20:00:17 |
| DataPoint Verified.                                    | (b) (4), (b) (6) | 06 Nov 2020 22:59:15 |
| User entered '10 Sep 2020'                             | (b) (4), (b) (6) | 15 Oct 2020 00:40:07 |

US3732262

**Folder:** Unscheduled 10 Sep 2020

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 11:12:45

[Collection time \(00:00-23:59\)](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Un-verified.                                 | (b) (4), (b) (6) | 09 Nov 2020 20:00:17 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 20:00:17 |
| DataPoint Verified.                                    | (b) (4), (b) (6) | 06 Nov 2020 22:59:15 |
| User entered '12:38'                                   | (b) (4), (b) (6) | 15 Oct 2020 00:40:07 |

US3732262

**Folder: Unscheduled 10 Sep 2020**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 11:12:45**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered empty.              | System | 09 Nov 2020 20:00:17 |
| User entered '10 Sep 2020 12:38' | System | 15 Oct 2020 00:40:07 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events Summary

**Generated On:** 26 Nov 2020 11:12:45

[Did the participant experience any adverse events?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 22:59:53 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Sep 2020 21:23:28 |

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:45

[AEID](#)

| Audit                                                                                                                                                                                              | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).              | (b) (4), (b) (6) | 23 Sep 2020 17:53:54 |
| Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' answered with 'updating' (Site from Safety). | (b) (4), (b) (6) | 22 Sep 2020 23:26:29 |
| User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).              | (b) (4), (b) (6) | 15 Sep 2020 18:43:26 |
| Reviewed for Safety.                                                                                                                                                                               | (b) (4), (b) (6) | 10 Sep 2020 16:26:28 |
| User entered 'USA-US102-2020-mRNA-1273-P301000001'                                                                                                                                                 | System           | 10 Sep 2020 16:25:56 |
| User entered 'New'                                                                                                                                                                                 | (b) (4), (b) (6) | 10 Sep 2020 16:25:56 |

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:45

[Adverse event](#)

| Audit                                                                                                                                                                                                                      | User                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.                                               | Coder Import (b) (4) | 23 Nov 2020 21:38:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                | Coder Import (b) (4) | 23 Nov 2020 21:38:17 |
| Data point term sent to Coder                                                                                                                                                                                              | System               | 23 Nov 2020 20:59:21 |
| Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.             | Coder Import (b) (4) | 23 Nov 2020 20:59:04 |
| ' canceled (Site from System).                                                                                                                                                                                             |                      |                      |
| User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. | Coder Import (b) (4) | 23 Nov 2020 12:23:56 |
| ' (Site from System).                                                                                                                                                                                                      |                      |                      |
| DataPoint Verified.                                                                                                                                                                                                        | (b) (4), (b) (6)     | 06 Nov 2020 23:00:51 |
| User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).                                      | (b) (4), (b) (6)     | 08 Oct 2020 13:57:16 |
| Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' answered with 'updated' (Site from Safety).                          | (b) (4), (b) (6)     | 07 Oct 2020 20:18:06 |
| User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).                                      | (b) (4), (b) (6)     | 29 Sep 2020 15:51:01 |
| User closed query 'PV Query: Please provide results of the baseline SARS-CoV-2 RT-PCR, and date results were received.' (Site from Safety).                                                                                | (b) (4), (b) (6)     | 23 Sep 2020 17:54:17 |
| User closed query 'PV query: Please clarify if subject was symptomatic prior receiving the first dose of study medication.' (Site from Safety).                                                                            | (b) (4), (b) (6)     | 23 Sep 2020 17:54:11 |

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:45

[Adverse event](#)

| Audit                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).                                                                                                                   | (b) (4), (b) (6) | 23 Sep 2020 17:54:04 |
| Query 'PV Query: Please provide results of the baseline SARS-CoV-2 RT-PCR, and date results were received.' answered with 'Baseline PCR was collected on 02SEP2020. Resulted as Positive on 08SEP2020' (Site from Safety).                            | (b) (4), (b) (6) | 22 Sep 2020 23:24:03 |
| Query 'PV query: Please clarify if subject was symptomatic prior receiving the first dose of study medication.' answered with 'Confirming subject was not symptomatic prior to receiving their first dose of IP ' (Site from Safety).                 | (b) (4), (b) (6) | 22 Sep 2020 23:21:20 |
| Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' answered with 'confirming subject did not have any known exposure COVID-19 or risk factors at the time of screening/baseline' (Site from Safety). | (b) (4), (b) (6) | 22 Sep 2020 23:18:46 |
| User opened query 'PV Query: Please provide results of the baseline SARS-CoV-2 RT-PCR, and date results were received.' (Site from Safety).                                                                                                           | (b) (4), (b) (6) | 16 Sep 2020 15:29:43 |
| User opened query 'PV query: Please clarify if subject was symptomatic prior receiving the first dose of study medication.' (Site from Safety).                                                                                                       | (b) (4), (b) (6) | 16 Sep 2020 15:28:56 |
| Query 'Safety Medical Query: Please provide results of the baseline SARS-CoV-2 RT-PCR, and date results were received.' canceled (Site from Safety).                                                                                                  | (b) (4), (b) (6) | 16 Sep 2020 15:28:08 |
| Query 'Safety Medical Query: Please clarify if subject was symptomatic prior receiving the first dose of study medication.' canceled (Site from Safety).                                                                                              | (b) (4), (b) (6) | 16 Sep 2020 15:27:56 |
| User opened query 'Safety Medical Query: Please provide results of the baseline SARS-CoV-2 RT-PCR, and date results were received.' (Site from Safety).                                                                                               | (b) (4), (b) (6) | 15 Sep 2020 18:46:44 |
| User opened query 'Safety Medical Query: Please clarify if subject was symptomatic prior receiving the first dose of study medication.' (Site from Safety).                                                                                           | (b) (4), (b) (6) | 15 Sep 2020 18:46:36 |
| User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).                                                                                                                   | (b) (4), (b) (6) | 15 Sep 2020 18:44:51 |

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:45

[Adverse event](#)

| Audit                                                                                                                                                                         | User                 | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0. | Coder Import (b) (4) | 10 Sep 2020 06:17:34 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                       | Coder Import (b) (4) | 10 Sep 2020 06:17:34 |
| Data point term sent to Coder                                                                                                                                                 | System               | 09 Sep 2020 22:21:54 |
| User entered 'Symptomatic COVID-19'                                                                                                                                           | (b) (4), (b) (6)     | 09 Sep 2020 22:20:54 |



US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Was this a medically-attended AE?](#)

| Audit                                                      | User             | Time (GMT)           |
|------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                        | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 30 Sep 2020 20:11:11 |
| User entered 'No (N)'                                      | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered 'No (N)' | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:45

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                                             | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'PV Query: Please confirm the start date of the SAE. The start date of the SAE should be when symptoms first are present.' (Site from Safety).                                                                                                                                                                  | (b) (4), (b) (6) | 07 Nov 2020 00:13:19 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| Query 'PV Query: Please confirm the start date of the SAE. The start date of the SAE should be when symptoms first are present.' answered with 'correct as is. Site was unaware when the symptoms first started, until positive baseline results were received and site called subject to notify of results.' (Site from Safety). | (b) (4), (b) (6) | 05 Nov 2020 18:19:34 |
| User opened query 'PV Query: Please confirm the start date of the SAE. The start date of the SAE should be when symptoms first are present.' (Site from Safety).                                                                                                                                                                  | (b) (4), (b) (6) | 12 Oct 2020 13:25:19 |
| Query 'PV Query: Please confirm the start date of the SAE. The start date of the SAE should be when symptoms first are present.' canceled (Site from Safety).                                                                                                                                                                     | (b) (4), (b) (6) | 12 Oct 2020 13:25:02 |
| User opened query 'PV Query: Please confirm the start date of the SAE. The start date of the SAE should be when symptoms first are present.' (Site from Safety).                                                                                                                                                                  | (b) (4), (b) (6) | 29 Sep 2020 15:52:48 |
| User entered '06 Sep 2020' reason for change: Data Entry Error                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 22 Sep 2020 23:13:42 |
| User entered '02 Sep 2020'                                                                                                                                                                                                                                                                                                        | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Start time \(00:00-23:59\)](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 23:13:42 |
| User entered '15:38'                                   | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[AE start date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered empty.              | System | 22 Sep 2020 23:13:42 |
| User entered '02 Sep 2020 15:38' | System | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Ongoing?](#)

| Audit                                                     | User             | Time (GMT)           |
|-----------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 30 Sep 2020 20:11:11 |
| User entered 'Yes (Y)'                                    | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

If not Ongoing, end date (*dd MMM yyyy*)

| Audit                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered '19 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 30 Sep 2020 20:11:11 |
| User entered empty.                                            | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |



US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[End time \(00:00-23:59\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered empty. | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:12:45**

[AE End Date and Time \(derived\)](#)

| Audit                                                                                                              | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Query 'PV Query: Please provide the event end date (when symptoms have resolved).' canceled (Site from Safety).    | (b) (4), (b) (6) | 12 Oct 2020 13:25:09 |
| User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety). | (b) (4), (b) (6) | 15 Sep 2020 18:43:43 |
| User entered empty.                                                                                                | System           | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Severity](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Is the adverse event serious?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered 'No (N)' | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:45

[Death](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered '0'    | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Life threatening](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered '0'    | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered '0'    | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered empty. | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |



US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered empty. | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Admitted to ICU?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered empty. | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Number of Days in ICU](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered empty. | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Persistent or significant disability or incapacity](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered '0'    | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Congenital anomaly or birth defect](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered '0'    | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Other medically important event](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered '0'    | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:45

[Relationship to investigational product](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'PV Query: Not applicable is not appropriate causality assessment. Per protocol, answer should be either a yes or no. Please provide the investigator's causality assessment between the event and the study drug' (Site from Safety).<br>DataPoint Verified. | (b) (4), (b) (6) | 07 Nov 2020 00:13:46 |
|                                                                                                                                                                                                                                                                                 | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User closed query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses' (Site from DM).                                         | (b) (4), (b) (6) | 06 Nov 2020 04:07:07 |
| Query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses' answered with 'updated' (Site from DM).                             | (b) (4), (b) (6) | 05 Nov 2020 19:03:33 |
| Query 'PV Query: Not applicable is not appropriate causality assessment. Per protocol, answer should be either a yes or no. Please provide the investigator's causality assessment between the event and the study drug' answered with 'Updated' (Site from Safety).            | (b) (4), (b) (6) | 05 Nov 2020 19:03:27 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error                                                                                                                                                                                                    | (b) (4), (b) (6) | 05 Nov 2020 19:03:08 |
| User opened query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses' (Site from DM).                                         | (b) (4), (b) (6) | 17 Oct 2020 13:22:38 |
| Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' canceled (Site from Safety).                                           | (b) (4), (b) (6) | 29 Sep 2020 15:52:18 |
| User opened query 'PV Query: Not applicable is not appropriate causality assessment. Per protocol, answer should be either a yes or no. Please provide the investigator's causality assessment between the event and the study drug' (Site from Safety).                        | (b) (4), (b) (6) | 15 Sep 2020 18:46:05 |

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:45

[Relationship to investigational product](#)

| Audit                                                                                                                                                                                                                                    | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety). | (b) (4), (b) (6) | 15 Sep 2020 18:45:31 |
| User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).                                                | System           | 09 Sep 2020 22:57:16 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error                                                                                                                                                       | (b) (4), (b) (6) | 09 Sep 2020 22:57:16 |
| User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).                                                | System           | 09 Sep 2020 22:20:54 |
| User entered 'Not Related (NOT RELATED)'                                                                                                                                                                                                 | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |



US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Relationship to Study Procedure](#)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:45

Action taken with investigational product

| Audit                                                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Per CDM: Dose discontinuation form has not been completed. Please reconcile. ' (Site from DM).                                                                                                                                                                                                     | (b) (4), (b) (6) | 09 Nov 2020 15:08:16 |
| User closed query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses ' (Site from DM).                                                                              | (b) (4), (b) (6) | 09 Nov 2020 15:08:14 |
| User closed query 'PV Query: Please confirm if the subject is scheduled to receive further IP doses? If no, please appropriately update Action Taken from None to Withdrawn per protocol.' (Site from Safety).                                                                                                        | (b) (4), (b) (6) | 07 Nov 2020 00:13:37 |
| Query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses ' answered with 'Correct as is. AE is not related to IP and IP for 2nd dose was withdrawn' (Site from DM). | (b) (4), (b) (6) | 06 Nov 2020 23:54:19 |
| Query 'Per CDM: Dose discontinuation form has not been completed. Please reconcile. ' answered with 'updated' (Site from DM).                                                                                                                                                                                         | (b) (4), (b) (6) | 06 Nov 2020 23:53:22 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User opened query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses ' (Site from DM).                                                                              | (b) (4), (b) (6) | 06 Nov 2020 19:04:47 |
| User opened query 'Per CDM: Dose discontinuation form has not been completed. Please reconcile. ' (Site from DM).                                                                                                                                                                                                     | (b) (4), (b) (6) | 06 Nov 2020 14:30:26 |
| Query 'PV Query: Please confirm if the subject is scheduled to receive further IP doses? If no, please appropriately update Action Taken from None to Withdrawn per protocol.' answered with 'updated' (Site from Safety).                                                                                            | (b) (4), (b) (6) | 05 Nov 2020 19:03:38 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error                                                                                                                                                                                                                      | (b) (4), (b) (6) | 05 Nov 2020 19:03:16 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:45

Action taken with investigational product

| Audit                                                                                                                                                                                                                                                                                                                                                                             | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose.' (Site from DM).                             | (b) (4), (b) (6) | 26 Oct 2020 10:09:39 |
| User opened query 'PV Query: Please confirm if the subject is scheduled to receive further IP doses? If no, please appropriately update Action Taken from None to Withdrawn per protocol.' (Site from Safety).                                                                                                                                                                    | (b) (4), (b) (6) | 21 Oct 2020 16:52:06 |
| User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).                                                                                                                                          | (b) (4), (b) (6) | 15 Oct 2020 14:14:40 |
| Query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose.' answered with 'Per CRA, correct as is.' (Site from DM). | (b) (4), (b) (6) | 14 Oct 2020 17:24:27 |
| Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'Per CRA, correct a is.' (Site from Safety).                                                                                                               | (b) (4), (b) (6) | 14 Oct 2020 17:24:08 |
| User entered 'None (NONE)' reason for change: Data Entry Error                                                                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 14 Oct 2020 17:23:43 |
| User opened query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose.' (Site from DM).                             | (b) (4), (b) (6) | 03 Oct 2020 18:33:36 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:45

[Action taken with investigational product](#)

| Audit                                                                                                                                                                                                                                    | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety). | (b) (4), (b) (6) | 29 Sep 2020 15:52:24 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error                                                                                                                                                       | (b) (4), (b) (6) | 09 Sep 2020 22:57:16 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)'                                                                                                                                                                             | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:45

None

| Audit                                                                                                                                                                                                                                                                                                                                                                                                   | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User closed query 'Per DM CLR: Other Action Taken = NONE. However, there is a Con Med recorded that has this AE as its indication. Please review and update eCRF as appropriate.' (Site from DM).                                                                                                                                                                                                       | (b) (4), (b) (6) | 26 Oct 2020 10:10:05 |
| Query 'Per DM CLR: Other Action Taken = NONE. However, there is a Con Med recorded that has this AE as its indication. Please review and update eCRF as appropriate.' answered with 'Updated.' (Site from DM).                                                                                                                                                                                          | (b) (4), (b) (6) | 14 Oct 2020 17:20:33 |
| User entered '0' reason for change: Data Entry Error                                                                                                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 14 Oct 2020 17:20:10 |
| 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) | 23 Sep 2020 17:54:29 |
| User opened query 'Per DM CLR: Other Action Taken = NONE. However, there is a Con Med recorded that has this AE as its indication. Please review and update eCRF as appropriate.' (Site from DM).                                                                                                                                                                                                       | (b) (4), (b) (6) | 23 Sep 2020 14:06:32 |
| 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 'please refer to medication list' (Site from Safety). | (b) (4), (b) (6) | 22 Sep 2020 23:27:06 |
| 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) | 15 Sep 2020 18:44:30 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[None](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '1' | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Concomitant Medication](#)

| Audit                                                | User             | Time (GMT)           |
|------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 14 Oct 2020 17:20:10 |
| User entered '0'                                     | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Concomitant Procedure](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered '0'    | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |



US3732262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:12:45

[Outcome](#)

| Audit                                                                                                                                                                                    | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                      | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).              | (b) (4), (b) (6) | 15 Oct 2020 14:14:51 |
| Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'Updated.' (Site from Safety). | (b) (4), (b) (6) | 14 Oct 2020 17:20:43 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error                                                                                               | (b) (4), (b) (6) | 14 Oct 2020 17:20:10 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).              | (b) (4), (b) (6) | 15 Sep 2020 18:44:09 |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                               | (b) (4), (b) (6) | 14 Sep 2020 14:47:02 |
| Query 'Data is required. Please complete.' answered with 'will be updated upon resolution' (Site from System).                                                                           | (b) (4), (b) (6) | 09 Sep 2020 22:59:53 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                               | System           | 09 Sep 2020 22:20:54 |
| User entered empty.                                                                                                                                                                      | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered empty. | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Narrative](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:00:51 |
| User entered empty. | (b) (4), (b) (6) | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 09 Sep 2020 22:20:54 |

US3732262

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 11:12:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 20:11:11 |
| User entered '0' | System | 09 Sep 2020 22:20:54 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 11:12:45**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | User                             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User closed query 'Per DM CLR: Per Diary Dose 1 Day 1-3 Pain at Injection Site; Day 1-2 Underarm Gland Swelling or Tenderness; and Day 4, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).                                                                             | (b) (4), (b) (6)                 | 09 Nov 2020 15:08:44 |
| Query 'Per DM CLR: Per Diary Dose 1 Day 1-3 Pain at Injection Site; Day 1-2 Underarm Gland Swelling or Tenderness; and Day 4, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Please refer to log line # 3- Tylenol previously recorded for headache ' (Site from DM). | (b) (4), (b) (6)                 | 06 Nov 2020 23:59:15 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)                 | 06 Nov 2020 23:01:17 |
| User opened query 'Per DM CLR: Per Diary Dose 1 Day 1-3 Pain at Injection Site; Day 1-2 Underarm Gland Swelling or Tenderness; and Day 4, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).                                                                             | (b) (4), (b) (6)                 | 06 Nov 2020 16:11:55 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:38:16 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                          | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                            | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: AGENTS<br>ACTING ON THE RENIN-ANGIOTENSIN<br>SYSTEM, ATC: ANGIOTENSIN II RECEPTOR<br>BLOCKERS (ARBS), PLAIN, ATC:<br>ANGIOTENSIN II RECEPTOR BLOCKERS<br>(ARBS), PLAIN, PRODUCT: LOSARTAN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 04 Sep 2020 18:41:38 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.                                                                                                                                                                                | Coder Import (b) (4)<br>(b) (4)  | 04 Sep 2020 18:41:38 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                  | System                           | 04 Sep 2020 18:40:32 |
| User entered 'losartan'                                                                                                                                                                                                                                                                        | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:39:32 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Prophylaxis](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:39:32 |



US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Indication](#)

| Audit                                                                                                                                                                                                                                                              | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).                                       | (b) (4), (b) (6)                 | 20 Oct 2020 19:22:10 |
| Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Reviewed and updated, per source.' (Site from DM). | (b) (4), (b) (6)                 | 13 Oct 2020 22:12:53 |
| User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).                                       | (b) (4), (b) (6)                 | 01 Oct 2020 11:01:17 |
| User entered 'hypertension'                                                                                                                                                                                                                                        | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:39:32 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Dose per administration](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| User entered '50'   | Lauren Arnett (b) (4) | 04 Sep 2020 18:39:32 |
|                     | (b) (4)               |                      |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Dose unit](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'mg (mg)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:39:32 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

[If dose unit is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:39:32 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Frequency](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| User entered 'once daily (QD)' | Lauren Arnett (b) (4) | 04 Sep 2020 18:39:32 |
|                                | (b) (4)               |                      |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

[If frequency is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:39:32 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| User entered 'Oral (ORAL)' | Lauren Arnett (b) (4) | 04 Sep 2020 18:39:32 |
|                            | (b) (4)               |                      |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

If route of administration is Other, specify

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:39:32 |



US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'un Jun 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:39:32 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| User entered '0'    | Lauren Arnett (b) (4) | 04 Sep 2020 18:39:32 |
|                     | (b) (4)               |                      |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Ongoing?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:39:32 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:39:32 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Was this medication taken for solicited event?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:39:32 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Sep 2020 18:39:32 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Sep 2020 18:39:32 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:12:45**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 04 Sep 2020 18:39:32 |



US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                  | User                             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| 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)  | 04 Sep 2020 18:41:38 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.                                                                                                                                                                        | Coder Import (b) (4)<br>(b) (4)  | 04 Sep 2020 18:41:38 |
| Data point term sent to Coder                                                                                                                                                                                                                                                          | System                           | 04 Sep 2020 18:40:37 |
| User entered 'ibuprofen'                                                                                                                                                                                                                                                               | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:40:03 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Prophylaxis](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| User entered 'No (N)' | Lauren Arnett (b) (4) | 04 Sep 2020 18:40:03 |
|                       | (b) (4)               |                      |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Indication](#)

| Audit                             | User                             | Time (GMT)           |
|-----------------------------------|----------------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'migraine headaches' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:40:03 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Dose per administration](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered '800'  | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:40:03 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Dose unit](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'mg (mg)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:40:03 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

[If dose unit is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:40:03 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Frequency](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'as needed (PRN)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:40:03 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

[If frequency is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:40:03 |



US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| User entered 'Oral (ORAL)' | Lauren Arnett (b) (4) | 04 Sep 2020 18:40:03 |
|                            | (b) (4)               |                      |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

If route of administration is Other, specify

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:40:03 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'un UNK 2017' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:40:03 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| User entered '0'    | Lauren Arnett (b) (4) | 04 Sep 2020 18:40:03 |
|                     | (b) (4)               |                      |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Ongoing?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:40:03 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:40:03 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Was this medication taken for solicited event?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 04 Sep 2020 18:40:03 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:40:03 |



US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:40:03 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:12:45**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 18:40:03 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Name of Medication](#)

| Audit                                                                                                                                                                                                    | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                      | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| 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)  | 11 Sep 2020 17:15:43 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                | Coder Import (b) (4)  | 11 Sep 2020 17:15:43 |
| Data point term sent to Coder                                                                                                                                                                            | System                | 11 Sep 2020 17:15:21 |
| User entered 'tylenol'                                                                                                                                                                                   | Lauren Arnett (b) (4) | 11 Sep 2020 17:15:12 |
|                                                                                                                                                                                                          | (b) (4)               |                      |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Prophylaxis](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 11 Sep 2020 17:15:12 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Indication](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. 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 of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Headache did not meet the AE reporting criteria.' (Site from DM).                                                                                                                        | (b) (4), (b) (6)                 | 20 Oct 2020 19:22:33 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. 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 of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Headache did not meet the AE reporting criteria.' answered with 'correct as is, no AE to be opened as AR did not meet reporting criteria however subject did take medication for AR' (Site from DM). | Lauren Arnett (b) (4)<br>(b) (4) | 20 Oct 2020 15:46:18 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. 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 of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Headache did not meet the AE reporting criteria.' (Site from DM).                                                                                                                        | (b) (4), (b) (6)                 | 01 Oct 2020 11:02:06 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Indication](#)

| Audit                                  | User                             | Time (GMT)           |
|----------------------------------------|----------------------------------|----------------------|
| User entered 'e-diary pain - headache' | Lauren Arnett (b) (4)<br>(b) (4) | 11 Sep 2020 17:15:12 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Dose per administration](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered '500'  | Lauren Arnett (b) (4)<br>(b) (4) | 11 Sep 2020 17:15:12 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Dose unit](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'mg (mg)' | Lauren Arnett (b) (4)<br>(b) (4) | 11 Sep 2020 17:15:12 |



US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[If dose unit is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 11 Sep 2020 17:15:12 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Frequency](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'as needed (PRN)' | Lauren Arnett (b) (4)<br>(b) (4) | 11 Sep 2020 17:15:12 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[If frequency is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 11 Sep 2020 17:15:12 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Route of administration](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'Oral (ORAL)' | Lauren Arnett (b) (4)<br>(b) (4) | 11 Sep 2020 17:15:12 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

If route of administration is Other, specify

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 11 Sep 2020 17:15:12 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered '04 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 11 Sep 2020 17:15:12 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 11 Sep 2020 17:15:12 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Ongoing?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 11 Sep 2020 17:15:12 |



US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered '04 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 11 Sep 2020 17:15:12 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Was this medication taken for solicited event?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 11 Sep 2020 17:15:12 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Sep 2020 17:15:12 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Sep 2020 17:15:12 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:12:45**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Sep 2020 17:15:12 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Name of Medication](#)

| Audit                                                                                                                                                                                                    | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                      | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| 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)  | 15 Sep 2020 19:05:49 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                | Coder Import (b) (4)  | 15 Sep 2020 19:05:49 |
| Data point term sent to Coder                                                                                                                                                                            | System                | 15 Sep 2020 19:05:00 |
| User entered 'tylenol'                                                                                                                                                                                   | Lauren Arnett (b) (4) | 15 Sep 2020 19:04:45 |
|                                                                                                                                                                                                          | (b) (4)               |                      |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Prophylaxis](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 19:04:45 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Indication](#)

| Audit                                                                                                                                                                                                                                                                                        | User                             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User closed query 'Per DM CLR: Please update Indication to specify the sign/symptom experienced by the patient. Please update all applicable details as appropriate. ' (Site from DM).                                                                                                       | (b) (4), (b) (6)                 | 20 Oct 2020 19:22:43 |
| Query 'Per DM CLR: Please update Indication to specify the sign/symptom experienced by the patient. Please update all applicable details as appropriate. ' answered with 'correct as is, per clarification AE of confirmed COVID is to be opened as "symptomatic covid-19" ' (Site from DM). | Lauren Arnett (b) (4)<br>(b) (4) | 20 Oct 2020 15:47:15 |
| User opened query 'Per DM CLR: Please update Indication to specify the sign/symptom experienced by the patient. Please update all applicable details as appropriate. ' (Site from DM).                                                                                                       | (b) (4), (b) (6)                 | 01 Oct 2020 11:02:49 |
| User entered 'symptomatic covid-19'                                                                                                                                                                                                                                                          | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 19:04:45 |



US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Dose per administration](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered '500'  | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 19:04:45 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Dose unit](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'mg (mg)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 19:04:45 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

[If dose unit is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 19:04:45 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Frequency](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'as needed (PRN)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 19:04:45 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

[If frequency is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 19:04:45 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Route of administration](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'Oral (ORAL)' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 19:04:45 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

If route of administration is Other, specify

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 19:04:45 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered '12 Sep 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 19:04:45 |



US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered '0'    | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 19:04:45 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Ongoing?](#)

| Audit                                                    | User                  | Time (GMT)           |
|----------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| User entered 'No (N)' reason for change: New Information | Lauren Arnett (b) (4) | 20 Oct 2020 15:48:23 |
| User entered 'Yes (Y)'                                   | Lauren Arnett (b) (4) | 15 Sep 2020 19:04:45 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                                                         | User                  | Time (GMT)           |
|---------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                           | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| User entered '19 Sep 2020' reason for change: New Information | Lauren Arnett (b) (4) | 20 Oct 2020 15:48:23 |
| User entered empty.                                           | Lauren Arnett (b) (4) | 15 Sep 2020 19:04:45 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Was this medication taken for solicited event?](#)

| Audit                                                                                                                                                                                                                                                                      | User                             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                        | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User closed query '<br>Per DM CLR: Note, Was this medication taken for<br>solicited event?' = Yes. However, associated<br>condition is not a Solicited Adverse Reaction per<br>Protocol 8.3.4. Review and update entry as<br>appropriate.' (Site from DM).                 | (b) (4), (b) (6)                 | 06 Nov 2020 04:07:37 |
| Query '<br>Per DM CLR: Note, Was this medication taken for<br>solicited event?' = Yes. However, associated<br>condition is not a Solicited Adverse Reaction per<br>Protocol 8.3.4. Review and update entry as<br>appropriate.' answered with 'updated ' (Site from<br>DM). | (b) (4), (b) (6)                 | 05 Nov 2020 19:13:10 |
| User entered 'No (N)' reason for change: Data Entry<br>Error                                                                                                                                                                                                               | (b) (4), (b) (6)                 | 05 Nov 2020 19:13:05 |
| User opened query '<br>Per DM CLR: Note, Was this medication taken for<br>solicited event?' = Yes. However, associated<br>condition is not a Solicited Adverse Reaction per<br>Protocol 8.3.4. Review and update entry as<br>appropriate.' (Site from DM).                 | (b) (4), (b) (6)                 | 30 Oct 2020 10:11:36 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                     | Lauren Arnett (b) (4)<br>(b) (4) | 15 Sep 2020 19:04:45 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 15 Sep 2020 19:04:45 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 15 Sep 2020 19:04:45 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:12:45**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 15 Sep 2020 19:04:45 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Name of Medication](#)

| Audit                                                                                                                                                                                                    | User                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                      | (b) (4), (b) (6)     | 06 Nov 2020 23:02:53 |
| 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) | 30 Sep 2020 20:16:41 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                | Coder Import (b) (4) | 30 Sep 2020 20:16:41 |
| Data point term sent to Coder                                                                                                                                                                            | System               | 30 Sep 2020 20:15:40 |
| User entered 'TYLENOL'                                                                                                                                                                                   | (b) (4), (b) (6)     | 30 Sep 2020 20:14:49 |



US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 20:14:49 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Indication](#)

| Audit                                                                                                                                                                                                                                                                       | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                         | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User closed query 'Per DM CLR: Please review Indication and please note, there is no corresponding AE record that match this condition. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).                                   | (b) (4), (b) (6) | 06 Nov 2020 04:08:02 |
| Query 'Per DM CLR: Please review Indication and please note, there is no corresponding AE record that match this condition. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' answered with 'indication is medical history' (Site from DM). | (b) (4), (b) (6) | 05 Nov 2020 19:14:59 |
| User opened query 'Per DM CLR: Please review Indication and please note, there is no corresponding AE record that match this condition. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).                                   | (b) (4), (b) (6) | 30 Oct 2020 19:29:06 |
| User entered 'MENSTRUAL CRAMPS'                                                                                                                                                                                                                                             | (b) (4), (b) (6) | 30 Sep 2020 20:14:49 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered '500'  | (b) (4), (b) (6) | 30 Sep 2020 20:14:49 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 30 Sep 2020 20:14:49 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 20:14:49 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 30 Sep 2020 20:14:49 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 20:14:49 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Route of administration](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 30 Sep 2020 20:15:02 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 30 Sep 2020 20:15:02 |
| User entered 'Oral (ORAL)' reason for change: Data Entry Error                         | (b) (4), (b) (6) | 30 Sep 2020 20:15:02 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 30 Sep 2020 20:14:49 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 30 Sep 2020 20:14:49 |



US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 20:14:49 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered 'UN UNK 2014' | (b) (4), (b) (6) | 30 Sep 2020 20:14:49 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered '0'    | (b) (4), (b) (6) | 30 Sep 2020 20:14:49 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 20:14:49 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 20:14:49 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 20:14:49 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 20:14:49 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 20:14:49 |



US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:12:45**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 20:14:49 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                  | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6)                | 06 Nov 2020 23:02:53 |
| 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) | 14 Oct 2020 07:21:22 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.                                                                                                                                                                             | Coder Import (b) (4)<br>(b) (4) | 14 Oct 2020 07:21:22 |
| Data point term sent to Coder                                                                                                                                                                                                                                                          | System                          | 13 Oct 2020 22:09:31 |
| User entered 'IBUPROFEN'                                                                                                                                                                                                                                                               | (b) (4), (b) (6)                | 13 Oct 2020 22:09:17 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered 'No (N)' | (b) (4), (b) (6) | 13 Oct 2020 22:09:17 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Indication](#)

| Audit                                                                                                                                                                                                                                                                                   | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User closed query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record that match this condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify.' (Site from DM).                                   | (b) (4), (b) (6) | 06 Nov 2020 04:08:45 |
| Query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record that match this condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify.' answered with 'indication is medical history' (Site from DM). | (b) (4), (b) (6) | 05 Nov 2020 19:15:38 |
| User opened query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record that match this condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify.' (Site from DM).                                   | (b) (4), (b) (6) | 30 Oct 2020 19:29:50 |
| User entered 'LEFT SPRAINED ANKLE'                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 13 Oct 2020 22:09:17 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered '800'  | (b) (4), (b) (6) | 13 Oct 2020 22:09:17 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 13 Oct 2020 22:09:17 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered empty. | (b) (4), (b) (6) | 13 Oct 2020 22:09:17 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 13 Oct 2020 22:09:17 |



US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered empty. | (b) (4), (b) (6) | 13 Oct 2020 22:09:17 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 13 Oct 2020 22:09:17 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered empty. | (b) (4), (b) (6) | 13 Oct 2020 22:09:17 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date \(dd MMM yyyy\)](#)

| Audit                                                         | User                  | Time (GMT)           |
|---------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                           | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| User entered 'UN Mar 2020' reason for change: DataEntry Error | Lauren Arnett (b) (4) | 20 Oct 2020 15:49:00 |
| User entered 'UN UNK 2020'                                    | (b) (4), (b) (6)      | 13 Oct 2020 22:09:17 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered '0'    | (b) (4), (b) (6) | 13 Oct 2020 22:09:17 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Oct 2020 22:09:17 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered empty. | (b) (4), (b) (6) | 13 Oct 2020 22:09:17 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 23:02:53 |
| User entered 'No (N)' | (b) (4), (b) (6) | 13 Oct 2020 22:09:17 |



US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Oct 2020 22:09:17 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Oct 2020 22:09:17 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:12:45**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Oct 2020 22:09:17 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Name of Medication](#)

| Audit                                                                                                                                                                                       | User                             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                         | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 05 Nov 2020 19:30:22 |
| 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)  | 05 Nov 2020 19:30:22 |
| Data point term sent to Coder                                                                                                                                                               | System                           | 05 Nov 2020 19:29:48 |
| User entered 'flu vaccine'                                                                                                                                                                  | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:29:06 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Prophylaxis](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'Yes (Y)' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:29:06 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Indication](#)

| Audit                    | User                             | Time (GMT)           |
|--------------------------|----------------------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'influenza' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:29:06 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Dose per administration](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered '0.5'  | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:29:06 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Dose unit](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'mL (mL)' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:29:06 |



US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

[If dose unit is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:29:06 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Frequency](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| User entered 'once (ONCE)' | Lauren Arnett (b) (4) | 05 Nov 2020 19:29:06 |
|                            | (b) (4)               |                      |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

[If frequency is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4) | 05 Nov 2020 19:29:06 |
|                     | (b) (4)               |                      |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Route of administration](#)

| Audit                                        | User                             | Time (GMT)           |
|----------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                          | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:29:06 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

If route of administration is Other, specify

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered empty. | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:29:06 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered '16 Oct 2020' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:29:06 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| User entered '0'    | Lauren Arnett (b) (4) | 05 Nov 2020 19:29:06 |
|                     | (b) (4)               |                      |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Ongoing?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 06 Nov 2020 23:02:53 |
| User entered 'No (N)' | Lauren Arnett (b) (4)<br>(b) (4) | 05 Nov 2020 19:29:06 |



US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| User entered '16 Oct 2020' | Lauren Arnett (b) (4) | 05 Nov 2020 19:29:06 |
|                            | (b) (4)               |                      |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Was this medication taken for solicited event?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 06 Nov 2020 23:02:53 |
| User entered 'No (N)' | Lauren Arnett (b) (4) | 05 Nov 2020 19:29:06 |
|                       | (b) (4)               |                      |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 19:29:06 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 19:29:06 |

US3732262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 11:12:45**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 19:29:06 |

US3732262

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 26 Nov 2020 11:12:45**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '06 Sep 2020' | (b) (4), (b) (6) | 06 Nov 2020 23:52:10 |
|                            |                  |                      |

US3732262

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 26 Nov 2020 11:12:45**

[Primary reason for dosing discontinuation](#)

| Audit                                                                                                                                                                                        | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Query 'Per CDM; Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' answered with 'correct as is. per previous directive of name of term for AE' (Site from DM). | (b) (4), (b) (6) | 24 Nov 2020 22:53:14 |
| User opened query 'Per CDM; Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' (Site from DM).                                                                  | (b) (4), (b) (6) | 18 Nov 2020 16:46:24 |
| User entered 'AE (specify) (ADVERSE EVENT)'                                                                                                                                                  | (b) (4), (b) (6) | 06 Nov 2020 23:52:10 |

US3732262

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 26 Nov 2020 11:12:45**

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| User entered 'Symptomatic COVID-19' | (b) (4), (b) (6) | 06 Nov 2020 23:52:10 |



US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered<br>'USA-US102-2020-MRNA-1273-P301000001' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Serious

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |



US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator's First Name](#)

| Audit                                   | User                  | Time (GMT)           |
|-----------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                     | (b) (4), (b) (6)      | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                    | (b) (4), (b) (6)      | 23 Sep 2020 17:55:45 |
| Amendment Manager: User entered 'Scott' | System                | 14 Sep 2020 21:58:34 |
| User entered 'Jeffrey'                  | Lauren Arnett (b) (4) | 10 Sep 2020 19:13:45 |
|                                         | (b) (4)               |                      |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator's Last Name](#)

| Audit                   | User                             | Time (GMT)           |
|-------------------------|----------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'Overcash' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [Street](#)

| Audit                                                      | User                  | Time (GMT)           |
|------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                        | (b) (4), (b) (6)      | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                       | (b) (4), (b) (6)      | 23 Sep 2020 17:55:45 |
| Amendment Manager: User entered '5565 Grossmont Center Dr' | System                | 14 Sep 2020 21:58:34 |
| User entered '5565 Grossmont Center Dr. BLD 2 Suite 1'     | Lauren Arnett (b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [City](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.   | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'La Mesa' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [State](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety. | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'CA'    | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [Postal Code](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety. | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered '91942' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator Country](#)

| Audit                                                  | User                  | Time (GMT)           |
|--------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)      | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                   | (b) (4), (b) (6)      | 08 Oct 2020 13:57:47 |
| Un-reviewed for Safety.                                | System                | 23 Sep 2020 17:55:57 |
| User entered 'US'                                      | System                | 23 Sep 2020 17:55:57 |
| Reviewed for Safety.                                   | (b) (4), (b) (6)      | 23 Sep 2020 17:55:45 |
| User entered empty; reason for change Data Entry Error | Lauren Arnett (b) (4) | 10 Sep 2020 19:17:53 |
| User entered 'US' (non-conformant).                    | System                | 10 Sep 2020 16:43:31 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:12:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 07 Nov 2020 00:14:22 |
| User entered '4' | System | 15 Oct 2020 14:15:10 |
| User entered '3' | System | 08 Oct 2020 13:57:59 |
| User entered '2' | System | 23 Sep 2020 17:55:57 |
| User entered '1' | System | 10 Sep 2020 16:43:31 |



US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered<br>'USA-US102-2020-MRNA-1273-P301000001' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Serious

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |



US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator's First Name](#)

| Audit                                   | User                  | Time (GMT)           |
|-----------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                     | (b) (4), (b) (6)      | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                    | (b) (4), (b) (6)      | 23 Sep 2020 17:55:45 |
| Amendment Manager: User entered 'Scott' | System                | 14 Sep 2020 21:58:34 |
| User entered 'Jeffrey'                  | Lauren Arnett (b) (4) | 10 Sep 2020 19:13:45 |
|                                         | (b) (4)               |                      |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator's Last Name](#)

| Audit                   | User                             | Time (GMT)           |
|-------------------------|----------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'Overcash' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [Street](#)

| Audit                                                      | User                             | Time (GMT)           |
|------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                        | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                       | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| Amendment Manager: User entered '5565 Grossmont Center Dr' | System                           | 14 Sep 2020 21:58:34 |
| User entered '5565 Grossmont Center Dr. BLD 2 Suite 1'     | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [City](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.   | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'La Mesa' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [State](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety. | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'CA'    | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [Postal Code](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety. | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered '91942' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator Country](#)

| Audit                                                  | User                  | Time (GMT)           |
|--------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)      | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                   | (b) (4), (b) (6)      | 08 Oct 2020 13:57:47 |
| Un-reviewed for Safety.                                | System                | 23 Sep 2020 17:55:57 |
| User entered 'US'                                      | System                | 23 Sep 2020 17:55:57 |
| Reviewed for Safety.                                   | (b) (4), (b) (6)      | 23 Sep 2020 17:55:45 |
| User entered empty; reason for change Data Entry Error | Lauren Arnett (b) (4) | 10 Sep 2020 19:17:53 |
| User entered 'US' (non-conformant).                    | System                | 10 Sep 2020 16:43:31 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:12:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 07 Nov 2020 00:14:22 |
| User entered '4' | System | 15 Oct 2020 14:15:10 |
| User entered '3' | System | 08 Oct 2020 13:57:59 |
| User entered '2' | System | 23 Sep 2020 17:55:57 |
| User entered '1' | System | 10 Sep 2020 16:43:31 |



US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form (1)

**Generated On:** 26 Nov 2020 11:12:45

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| User entered '10/Sep/2020 12:43' | System           | 10 Sep 2020 16:43:31 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:12:45

**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) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 17:55:45 |
| User entered '1'     | (b) (4), (b) (6) | 10 Sep 2020 16:43:31 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered<br>'USA-US102-2020-MRNA-1273-P301000001' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Serious

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:12:45

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |



US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator's First Name](#)

| Audit                                   | User                  | Time (GMT)           |
|-----------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                     | (b) (4), (b) (6)      | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                    | (b) (4), (b) (6)      | 23 Sep 2020 17:55:45 |
| Amendment Manager: User entered 'Scott' | System                | 14 Sep 2020 21:58:34 |
| User entered 'Jeffrey'                  | Lauren Arnett (b) (4) | 10 Sep 2020 19:13:45 |
|                                         | (b) (4)               |                      |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator's Last Name](#)

| Audit                   | User                             | Time (GMT)           |
|-------------------------|----------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'Overcash' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [Street](#)

| Audit                                                      | User                  | Time (GMT)           |
|------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                        | (b) (4), (b) (6)      | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                       | (b) (4), (b) (6)      | 23 Sep 2020 17:55:45 |
| Amendment Manager: User entered '5565 Grossmont Center Dr' | System                | 14 Sep 2020 21:58:34 |
| User entered '5565 Grossmont Center Dr. BLD 2 Suite 1'     | Lauren Arnett (b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [City](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.   | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'La Mesa' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [State](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety. | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'CA'    | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:12:45

[Site Address: Postal Code](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety. | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered '91942' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |



US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator Country](#)

| Audit                                                  | User                  | Time (GMT)           |
|--------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)      | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                   | (b) (4), (b) (6)      | 08 Oct 2020 13:57:47 |
| Un-reviewed for Safety.                                | System                | 23 Sep 2020 17:55:57 |
| User entered 'US'                                      | System                | 23 Sep 2020 17:55:57 |
| Reviewed for Safety.                                   | (b) (4), (b) (6)      | 23 Sep 2020 17:55:45 |
| User entered empty; reason for change Data Entry Error | Lauren Arnett (b) (4) | 10 Sep 2020 19:17:53 |
| User entered 'US' (non-conformant).                    | System                | 10 Sep 2020 16:43:31 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:12:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 07 Nov 2020 00:14:22 |
| User entered '4' | System | 15 Oct 2020 14:15:10 |
| User entered '3' | System | 08 Oct 2020 13:57:59 |
| User entered '2' | System | 23 Sep 2020 17:55:57 |
| User entered '1' | System | 10 Sep 2020 16:43:31 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form (2)

**Generated On:** 26 Nov 2020 11:12:45

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| User entered '23/Sep/2020 13:55' | System           | 23 Sep 2020 17:55:57 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:12:45

**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) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Oct 2020 13:57:47 |
| User entered '1'     | (b) (4), (b) (6) | 23 Sep 2020 17:55:57 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered<br>'USA-US102-2020-MRNA-1273-P301000001' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Serious

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |



US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:12:45

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator's First Name](#)

| Audit                                   | User                  | Time (GMT)           |
|-----------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                     | (b) (4), (b) (6)      | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                    | (b) (4), (b) (6)      | 23 Sep 2020 17:55:45 |
| Amendment Manager: User entered 'Scott' | System                | 14 Sep 2020 21:58:34 |
| User entered 'Jeffrey'                  | Lauren Arnett (b) (4) | 10 Sep 2020 19:13:45 |
|                                         | (b) (4)               |                      |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator's Last Name](#)

| Audit                   | User                             | Time (GMT)           |
|-------------------------|----------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'Overcash' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [Street](#)

| Audit                                                      | User                             | Time (GMT)           |
|------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                        | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                       | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| Amendment Manager: User entered '5565 Grossmont Center Dr' | System                           | 14 Sep 2020 21:58:34 |
| User entered '5565 Grossmont Center Dr. BLD 2 Suite 1'     | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [City](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.   | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'La Mesa' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |



US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [State](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety. | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'CA'    | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [Postal Code](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety. | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered '91942' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator Country](#)

| Audit                                                  | User                  | Time (GMT)           |
|--------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)      | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                   | (b) (4), (b) (6)      | 08 Oct 2020 13:57:47 |
| Un-reviewed for Safety.                                | System                | 23 Sep 2020 17:55:57 |
| User entered 'US'                                      | System                | 23 Sep 2020 17:55:57 |
| Reviewed for Safety.                                   | (b) (4), (b) (6)      | 23 Sep 2020 17:55:45 |
| User entered empty; reason for change Data Entry Error | Lauren Arnett (b) (4) | 10 Sep 2020 19:17:53 |
| User entered 'US' (non-conformant).                    | System                | 10 Sep 2020 16:43:31 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:12:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 07 Nov 2020 00:14:22 |
| User entered '4' | System | 15 Oct 2020 14:15:10 |
| User entered '3' | System | 08 Oct 2020 13:57:59 |
| User entered '2' | System | 23 Sep 2020 17:55:57 |
| User entered '1' | System | 10 Sep 2020 16:43:31 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form (3)

**Generated On:** 26 Nov 2020 11:12:45

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| User entered '08/Oct/2020 13:57' | System           | 08 Oct 2020 13:57:59 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:12:45

**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) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety. | (b) (4), (b) (6) | 15 Oct 2020 14:15:01 |
| User entered '1'     | (b) (4), (b) (6) | 08 Oct 2020 13:57:59 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered<br>'USA-US102-2020-MRNA-1273-P301000001' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Serious

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |



US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator's First Name](#)

| Audit                                   | User                  | Time (GMT)           |
|-----------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                     | (b) (4), (b) (6)      | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                    | (b) (4), (b) (6)      | 23 Sep 2020 17:55:45 |
| Amendment Manager: User entered 'Scott' | System                | 14 Sep 2020 21:58:34 |
| User entered 'Jeffrey'                  | Lauren Arnett (b) (4) | 10 Sep 2020 19:13:45 |
|                                         | (b) (4)               |                      |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator's Last Name](#)

| Audit                   | User                             | Time (GMT)           |
|-------------------------|----------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'Overcash' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |



US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [Street](#)

| Audit                                                      | User                             | Time (GMT)           |
|------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                        | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                       | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| Amendment Manager: User entered '5565 Grossmont Center Dr' | System                           | 14 Sep 2020 21:58:34 |
| User entered '5565 Grossmont Center Dr. BLD 2 Suite 1'     | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [City](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.   | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'La Mesa' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [State](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety. | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'CA'    | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [Postal Code](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety. | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered '91942' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator Country](#)

| Audit                                                  | User                  | Time (GMT)           |
|--------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)      | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                   | (b) (4), (b) (6)      | 08 Oct 2020 13:57:47 |
| Un-reviewed for Safety.                                | System                | 23 Sep 2020 17:55:57 |
| User entered 'US'                                      | System                | 23 Sep 2020 17:55:57 |
| Reviewed for Safety.                                   | (b) (4), (b) (6)      | 23 Sep 2020 17:55:45 |
| User entered empty; reason for change Data Entry Error | Lauren Arnett (b) (4) | 10 Sep 2020 19:17:53 |
| User entered 'US' (non-conformant).                    | System                | 10 Sep 2020 16:43:31 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:12:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 07 Nov 2020 00:14:22 |
| User entered '4' | System | 15 Oct 2020 14:15:10 |
| User entered '3' | System | 08 Oct 2020 13:57:59 |
| User entered '2' | System | 23 Sep 2020 17:55:57 |
| User entered '1' | System | 10 Sep 2020 16:43:31 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form (4)

**Generated On:** 26 Nov 2020 11:12:45

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| User entered '15/Oct/2020 10:15' | System           | 15 Oct 2020 14:15:10 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:12:45

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Nov 2020 00:14:11 |
| DataPoint Verified.  | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| User entered '1'     | (b) (4), (b) (6) | 15 Oct 2020 14:15:10 |
|                      |                  |                      |
|                      |                  |                      |



US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered<br>'USA-US102-2020-MRNA-1273-P301000001' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Serious

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:12:45

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:12:45

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 10 Sep 2020 16:43:24 |
| User entered 'No (N)' | System           | 10 Sep 2020 16:25:56 |



US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator's First Name](#)

| Audit                                   | User                  | Time (GMT)           |
|-----------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                     | (b) (4), (b) (6)      | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                    | (b) (4), (b) (6)      | 23 Sep 2020 17:55:45 |
| Amendment Manager: User entered 'Scott' | System                | 14 Sep 2020 21:58:34 |
| User entered 'Jeffrey'                  | Lauren Arnett (b) (4) | 10 Sep 2020 19:13:45 |
|                                         | (b) (4)               |                      |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator's Last Name](#)

| Audit                   | User                             | Time (GMT)           |
|-------------------------|----------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.    | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'Overcash' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [Street](#)

| Audit                                                      | User                  | Time (GMT)           |
|------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                        | (b) (4), (b) (6)      | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                       | (b) (4), (b) (6)      | 23 Sep 2020 17:55:45 |
| Amendment Manager: User entered '5565 Grossmont Center Dr' | System                | 14 Sep 2020 21:58:34 |
| User entered '5565 Grossmont Center Dr. BLD 2 Suite 1'     | Lauren Arnett (b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [City](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.   | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'La Mesa' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [State](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety. | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered 'CA'    | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

Site Address: [Postal Code](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                 | 06 Nov 2020 22:59:33 |
| Reviewed for Safety. | (b) (4), (b) (6)                 | 23 Sep 2020 17:55:45 |
| User entered '91942' | Lauren Arnett (b) (4)<br>(b) (4) | 10 Sep 2020 19:13:45 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:12:45

[Investigator Country](#)

| Audit                                                  | User                  | Time (GMT)           |
|--------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)      | 06 Nov 2020 22:59:33 |
| Reviewed for Safety.                                   | (b) (4), (b) (6)      | 08 Oct 2020 13:57:47 |
| Un-reviewed for Safety.                                | System                | 23 Sep 2020 17:55:57 |
| User entered 'US'                                      | System                | 23 Sep 2020 17:55:57 |
| Reviewed for Safety.                                   | (b) (4), (b) (6)      | 23 Sep 2020 17:55:45 |
| User entered empty; reason for change Data Entry Error | Lauren Arnett (b) (4) | 10 Sep 2020 19:17:53 |
| User entered 'US' (non-conformant).                    | System                | 10 Sep 2020 16:43:31 |

US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 11:12:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 07 Nov 2020 00:14:22 |
| User entered '4' | System | 15 Oct 2020 14:15:10 |
| User entered '3' | System | 08 Oct 2020 13:57:59 |
| User entered '2' | System | 23 Sep 2020 17:55:57 |
| User entered '1' | System | 10 Sep 2020 16:43:31 |



US3732262

**Folder:** SAE USA-US102-2020-MRNA-1273-P301000001

**Form:** Safety Report Form (5)

**Generated On:** 26 Nov 2020 11:12:45

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 10 Nov 2020 18:26:44 |
| User entered '06/Nov/2020 19:14' | System           | 07 Nov 2020 00:14:22 |

US3732262

Folder: SAE USA-US102-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:12:45

**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) | 10 Nov 2020 18:26:44 |
| User entered '1'    | (b) (4), (b) (6) | 07 Nov 2020 00:14:22 |