

US3462255 (Prod: Crisor, LLC)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:31:59

All time stamps listed in this document are displayed in GMT

US3462255

**Form: Participant Creation**

**Generated On: 26 Nov 2020 09:31:59**

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[Participant ID](#)

US3462255

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

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US3462255

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:59

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 19 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | SCRN                                    |

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:59

|                                           |                                                                                                                                                                            |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy)                  | (b) (6) 1962                                                                                                                                                               |
| Age                                       | 57                                                                                                                                                                         |
| Age Units                                 | YEARS                                                                                                                                                                      |
| Age (Derived)                             | 57                                                                                                                                                                         |
| Sex                                       | Female <input checked="" type="radio"/><br>Male <input type="radio"/>                                                                                                      |
| Ethnicity                                 | Hispanic or Latino <input type="radio"/><br>Not Hispanic or Latino <input checked="" type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |                                                                                                                                                                            |
| White                                     | True                                                                                                                                                                       |
| Black                                     | False                                                                                                                                                                      |
| Asian                                     | False                                                                                                                                                                      |
| American Indian or Alaska Native          | False                                                                                                                                                                      |
| Native Hawaiian or other Pacific Islander | False                                                                                                                                                                      |
| Other                                     | False                                                                                                                                                                      |
| If race is Other, specify _____           |                                                                                                                                                                            |
| Unknown                                   | False                                                                                                                                                                      |
| Not reported                              | False                                                                                                                                                                      |

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:59

|                                                 |                                              |
|-------------------------------------------------|----------------------------------------------|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 19 AUG 2020                                  |
| Month and Year of Informed Consent (derived)    | AUG 2020                                     |
| Year of Informed Consent (derived)              | 2020                                         |
| Protocol Version                                | Amendment 1 <input type="radio"/>            |
|                                                 | Amendment 2 <input checked="" type="radio"/> |
|                                                 | Amendment 3 <input type="radio"/>            |
|                                                 | Amendment 4 <input type="radio"/>            |
|                                                 | Amendment 5 <input type="radio"/>            |
| Was participant enrolled in the study?          | Yes <input checked="" type="radio"/>         |
|                                                 | No <input type="radio"/>                     |
| If No, indicate reason for screen fail          | Withdrew Consent <input type="radio"/>       |
|                                                 | Inclusion/Exclusion <input type="radio"/>    |
|                                                 | Cohort Full <input type="radio"/>            |
|                                                 | Other <input type="radio"/>                  |
| If reason for screen fail is Other, specify     |                                              |
| Was this participant screened previously?       | Yes <input type="radio"/>                    |
|                                                 | No <input checked="" type="radio"/>          |
| If Yes, previous participant number             |                                              |
| Enrollment Trigger                              | 1                                            |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:31:59

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:31:59

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

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|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | DIABETES MELLITUS (TYPE 2)                                       |
| Start date (dd MMM yyyy)                          | UN UNK 2011                                                      |
| 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 2011                                                         |
| Start Year (derived)                              | 2011                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |



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Folder: Screening

Form: Medical History (2)

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|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | SEASONAL ALLERGIC RHINITIS<br>/ PERENNIAL ALLERGIC<br>RHINITIS   |
| Start date (dd MMM yyyy)                          | UN UNK 1980                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 1980                                                         |
| Start Year (derived)                              | 1980                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:59

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | HYPERTENSION                                                     |
| Start date (dd MMM yyyy)                          | UN UNK 1995                                                      |
| 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 1995                                                         |
| Start Year (derived)                              | 1995                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Form: Medical History (4)

Generated On: 26 Nov 2020 09:31:59

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

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:31:59

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | GASTROESOPHOGEAL REFLUX<br>DISEASE                               |
| Start date (dd MMM yyyy)                          | UN UNK 1995                                                      |
| 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 1995                                                         |
| Start Year (derived)                              | 1995                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:31:59

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | HYPERCHOLESTEROLEMIA                                             |
| Start date (dd MMM yyyy)                          | UN UNK 2010                                                      |
| 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 2010                                                         |
| Start Year (derived)                              | 2010                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:31:59

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | OSTEOARTHRITIS (BILATERAL KNEES)                                 |
| Start date (dd MMM yyyy)                          | UN UNK 2005                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2005                                                         |
| Start Year (derived)                              | 2005                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:31:59

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | BILATERAL CARPEL TUNNEL                                          |
| Start date (dd MMM yyyy)                          | UN UNK 1985                                                      |
| 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 1988                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 1985                                                         |
| Start Year (derived)                              | 1985                                                             |
| Stop Month and Year (derived)                     | JAN 1988                                                         |
| Stop Year (derived)                               | 1988                                                             |

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:31:59

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | TORN RIGHT LATERAL<br>MENISCUS                                   |
| Start date (dd MMM yyyy)                          | UN UNK 2008                                                      |
| 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 2009                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2008                                                         |
| Start Year (derived)                              | 2008                                                             |
| Stop Month and Year (derived)                     | JAN 2009                                                         |
| Stop Year (derived)                               | 2009                                                             |



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Form: Medical History (10)

Generated On: 26 Nov 2020 09:31:59

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

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:31:59

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | MILD OBESTIY                                                     |
| Start date (dd MMM yyyy)                          | UN UNK 2010                                                      |
| 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 2010                                                         |
| Start Year (derived)                              | 2010                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:31:59

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | LOWER BACK PAIN                                                  |
| Start date (dd MMM yyyy)                          | UN JUL 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)                    | JUL 2020                                                         |
| Start Year (derived)                              | 2020                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:31:59

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | CESAREAN SECTION                                                 |
| Start date (dd MMM yyyy)                          | UN UNK 1982                                                      |
| 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 1982                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 1982                                                         |
| Start Year (derived)                              | 1982                                                             |
| Stop Month and Year (derived)                     | JAN 1982                                                         |
| Stop Year (derived)                               | 1982                                                             |

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:31:59

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | CESAREAN SECTION                                                 |
| Start date (dd MMM yyyy)                          | UN UNK 1988                                                      |
| 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 1988                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 1988                                                         |
| Start Year (derived)                              | 1988                                                             |
| Stop Month and Year (derived)                     | JAN 1988                                                         |
| Stop Year (derived)                               | 1988                                                             |

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:31:59

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | BILATERAL CARPEL TUNNEL REPAIR                                   |
| Start date (dd MMM yyyy)                          | UN UNK 1988                                                      |
| 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 1988                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 1988                                                         |
| Start Year (derived)                              | 1988                                                             |
| Stop Month and Year (derived)                     | JAN 1988                                                         |
| Stop Year (derived)                               | 1988                                                             |

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:31:59

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | RIGHT LATERAL MENISCUS<br>REPAIR                                 |
| Start date (dd MMM yyyy)                          | UN UNK 2009                                                      |
| 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 2009                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2009                                                         |
| Start Year (derived)                              | 2009                                                             |
| Stop Month and Year (derived)                     | JAN 2009                                                         |
| Stop Year (derived)                               | 2009                                                             |

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:59

|                                           |                                      |
|-------------------------------------------|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|                                           | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 19 AUG 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 13:53 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 19 AUG 2020 13:53                    |
| Height ( <i>xxx.x</i> )                   | 165 cm                               |
| Weight ( <i>xxx.x</i> )                   | 105 kg                               |
| BMI ( <i>xxx.x</i> )                      | 38.56749 kg/m <sup>2</sup>           |
| BMI units                                 | KG/M2                                |
| Temperature ( <i>xxx.x</i> )              | ND - Not Done                        |
| Route of measurement                      | Oral <input type="radio"/>           |
|                                           | Axillary <input type="radio"/>       |
|                                           | Other <input type="radio"/>          |
| If Other, specify                         |                                      |
| Pulse ( <i>xxx</i> )                      | ND - Not Done                        |
| Pulse units                               | BPM                                  |
| Respiratory Rate ( <i>xxx</i> )           | ND - Not Done                        |
| Respiratory Rate units                    | BREATHS/MIN                          |
| Systolic Blood Pressure ( <i>xxx</i> )    | ND - Not Done                        |
| Systolic Blood Pressure units             | MMHG                                 |
| Diastolic Blood Pressure ( <i>xxx</i> )   | ND - Not Done                        |
| Diastolic Blood Pressure units            | MMHG                                 |
| Height (derived)                          |                                      |
| Weight (derived)                          |                                      |



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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:31:59

Date of assessment (*dd MMM yyyy*) 19 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN UNK 1988

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:59

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 19 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | VISIT1                                  |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:59

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 144306

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:59

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:59

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 19 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 13:53 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 19 AUG 2020 13:53                                                                                      |
| Temperature (xxx.x)                 | 98.9 F                                                                                                 |
| Route of measurement                | Oral <input type="radio"/><br>Axillary <input type="radio"/><br>Other <input checked="" type="radio"/> |
| If Other, specify                   | TYMPANIC                                                                                               |
| Pulse (xxx)                         | 84 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 16 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 126 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 76 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |



US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:59

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 19 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 15:10 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 19 AUG 2020 15:10                                                                                      |
| Temperature (xxx.x)                 | 99 F                                                                                                   |
| Route of measurement                | Oral <input type="radio"/><br>Axillary <input type="radio"/><br>Other <input checked="" type="radio"/> |
| If Other, specify                   | TYMPANIC                                                                                               |
| Pulse (xxx)                         | 88 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 16 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 140 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 84 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

US3462255

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:59

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.*

US3462255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:59

|                                                                                                              |                                                                    |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| Was study treatment given?                                                                                   | Yes <input checked="" type="radio"/>                               |
|                                                                                                              | No <input type="radio"/>                                           |
| If No, reason not given                                                                                      | Participant declined due to Adverse Event <input type="radio"/>    |
|                                                                                                              | Physician withheld dose due to Adverse Event <input type="radio"/> |
|                                                                                                              | Death <input type="radio"/>                                        |
|                                                                                                              | Lost To Follow-Up <input type="radio"/>                            |
|                                                                                                              | Physician Decision <input type="radio"/>                           |
|                                                                                                              | Pregnancy <input type="radio"/>                                    |
|                                                                                                              | Protocol Deviation <input type="radio"/>                           |
|                                                                                                              | Study Terminated by Sponsor <input type="radio"/>                  |
|                                                                                                              | Withdrawal of Consent by Participant <input type="radio"/>         |
|                                                                                                              | Confirmed COVID-19 <input type="radio"/>                           |
|                                                                                                              | Other <input type="radio"/>                                        |
| If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify |                                                                    |
| What was the study treatment?                                                                                | MRNA-1273 OR PLACEBO                                               |
| What was the treatment date? (dd MMM yyyy)                                                                   | 19 AUG 2020                                                        |
| What was the treatment time? (00:00-23:59)                                                                   | 14:38 (24 HR)                                                      |
| Treatment Date and Time (derived)                                                                            | 19 AUG 2020 14:38                                                  |
| 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                                                      |

US3462255

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:59

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

19 AUG 2020

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

14:33 (24 HR)

Collection date and time (derived)

19 AUG 2020 14:33

US3462255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:31:59

|                                        |                           |                                          |                                    |
|----------------------------------------|---------------------------|------------------------------------------|------------------------------------|
| Collection date ( <i>dd MMM yyyy</i> ) |                           |                                          | 19 AUG 2020                        |
| Lab Test                               | Was the sample collected? | Collection time ( <i>00:00 - 23:59</i> ) | Collection date and time (derived) |
| Nasopharyngeal Swab 1                  | Yes                       | 14:30                                    | 19 AUG 2020 14:30                  |
| Nasopharyngeal Swab 2                  | No                        |                                          |                                    |

US3462255

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:31:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

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**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

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

19 AUG 2020 15:12

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PC Open Date & Time

19 AUG 2020 14:58

---

PC Close Date & Time

19 AUG 2020 17:28

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US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp 19 AUG 2020 18:41

PC Open Date & Time 19 AUG 2020 18:23

PC Close Date & Time 20 AUG 2020 11:59



US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:31:59

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

20 AUG 2020 17:14

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:31:59

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

21 AUG 2020 20:21

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:31:59

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

22 AUG 2020 17:00

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:31:59

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

23 AUG 2020 17:14

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:31:59

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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

98.5 °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

24 AUG 2020 16:33

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:31:59

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 03:18

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**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

19 AUG 2020 15:10

PC Open Date & Time

19 AUG 2020 14:58

PC Close Date & Time

19 AUG 2020 17:28

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**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

19 AUG 2020 18:39

PC Open Date & Time

19 AUG 2020 18:23

PC Close Date & Time

20 AUG 2020 11:59



US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**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

20 AUG 2020 17:14

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:31:59

**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

21 AUG 2020 20:21

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 17:00

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 17:15

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**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

24 AUG 2020 16:33

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**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

26 AUG 2020 03:19

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**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 ☐

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 19 AUG 2020 15:11 |
| PC Open Date & Time  | 19 AUG 2020 14:58 |
| PC Close Date & Time | 19 AUG 2020 17:28 |



US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**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 ☐

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 19 AUG 2020 18:40 |
| PC Open Date & Time  | 19 AUG 2020 18:23 |
| PC Close Date & Time | 20 AUG 2020 11:59 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**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 ☒

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 20 AUG 2020 17:15 |
| PC Open Date & Time          | 20 AUG 2020 12:00 |
| PC Close Date & Time         | 21 AUG 2020 11:59 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

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 ☒

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 21 AUG 2020 20:22 |
| PC Open Date & Time          | 21 AUG 2020 12:00 |
| PC Close Date & Time         | 22 AUG 2020 11:59 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**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 ☒

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 22 AUG 2020 17:01 |
| PC Open Date & Time          | 22 AUG 2020 12:00 |
| PC Close Date & Time         | 23 AUG 2020 11:59 |



US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

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 ☒

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 23 AUG 2020 17:15 |
| PC Open Date & Time          | 23 AUG 2020 12:00 |
| PC Close Date & Time         | 24 AUG 2020 11:59 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

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 ☒

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 24 AUG 2020 16:34 |
| PC Open Date & Time          | 24 AUG 2020 12:00 |
| PC Close Date & Time         | 25 AUG 2020 11:59 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

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 ☒

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 26 AUG 2020 03:19 |
| PC Open Date & Time          | 25 AUG 2020 12:00 |
| PC Close Date & Time         | 26 AUG 2020 11:59 |

US3462255

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462255

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3462255

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:59

Was Contact Attempted?

Yes ☒

No ☐

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

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462255

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:59

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*

US3462255

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:59

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 16 SEP 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | VISIT2                                  |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:59

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| Timepoint                           | Pre-Dose <input checked="" type="radio"/> |
|                                     | Post-Dose <input type="radio"/>           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of assessment (dd MMM yyyy)    | 16 SEP 2020                               |
| Time of assessment (00:00-23:59)    | 13:14 (24 HR)                             |
| Vital Signs Date and Time (derived) | 16 SEP 2020 13:14                         |
| Temperature (xxx.x)                 | 97.3 F                                    |
| Route of measurement                | Oral <input type="radio"/>                |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input checked="" type="radio"/>    |
| If Other, specify                   | TYMPANIC                                  |
| Pulse (xxx)                         | 90 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 16 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 130 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 74 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:59

|                                     |                                            |
|-------------------------------------|--------------------------------------------|
| Timepoint                           | Pre-Dose <input type="radio"/>             |
|                                     | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>       |
|                                     | No <input type="radio"/>                   |
| Date of assessment (dd MMM yyyy)    | 16 SEP 2020                                |
| Time of assessment (00:00-23:59)    | 14:16 (24 HR)                              |
| Vital Signs Date and Time (derived) | 16 SEP 2020 14:16                          |
| Temperature (xxx.x)                 | 98.9 F                                     |
| Route of measurement                | Oral <input type="radio"/>                 |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input checked="" type="radio"/>     |
| If Other, specify                   | TYMPANIC                                   |
| Pulse (xxx)                         | 90 beats/min                               |
| Pulse units                         | BPM                                        |
| Respiratory Rate (xxx)              | 18 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 124 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 78 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:59

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.*



US3462255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:59

|                                                                                                              |                                                                    |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| Was study treatment given?                                                                                   | Yes <input checked="" type="radio"/>                               |
|                                                                                                              | No <input type="radio"/>                                           |
| If No, reason not given                                                                                      | Participant declined due to Adverse Event <input type="radio"/>    |
|                                                                                                              | Physician withheld dose due to Adverse Event <input type="radio"/> |
|                                                                                                              | Death <input type="radio"/>                                        |
|                                                                                                              | Lost To Follow-Up <input type="radio"/>                            |
|                                                                                                              | Physician Decision <input type="radio"/>                           |
|                                                                                                              | Pregnancy <input type="radio"/>                                    |
|                                                                                                              | Protocol Deviation <input type="radio"/>                           |
|                                                                                                              | Study Terminated by Sponsor <input type="radio"/>                  |
|                                                                                                              | Withdrawal of Consent by Participant <input type="radio"/>         |
|                                                                                                              | Confirmed COVID-19 <input type="radio"/>                           |
|                                                                                                              | Other <input type="radio"/>                                        |
| If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify |                                                                    |
| What was the study treatment?                                                                                | MRNA-1273 OR PLACEBO                                               |
| What was the treatment date? (dd MMM yyyy)                                                                   | 16 SEP 2020                                                        |
| What was the treatment time? (00:00-23:59)                                                                   | 13:44 (24 HR)                                                      |
| Treatment Date and Time (derived)                                                                            | 16 SEP 2020 13:44                                                  |
| 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                                                      |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:59

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 16 SEP 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 14:16 (24 HR)                        |
| Collection date and time (derived)     | 16 SEP 2020 14:16                    |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:31:59

| Collection date (dd MMM yyyy) |                           |                                 | 16 SEP 2020                        |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 13:31                           | 16 SEP 2020 13:31                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

---

**TIMEPOINT**

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

---

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.9 °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

16 SEP 2020 14:20

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PC Open Date & Time

16 SEP 2020 14:04

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PC Close Date & Time

16 SEP 2020 16:34

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US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp 16 SEP 2020 18:06

PC Open Date & Time 16 SEP 2020 17:29

PC Close Date & Time 17 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:31:59

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

17 SEP 2020 18:33

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:31:59

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.2 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

18 SEP 2020 18:42

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PC Open Date & Time

18 SEP 2020 12:00

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PC Close Date & Time

19 SEP 2020 11:59

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US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:31:59

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

19 SEP 2020 19:35

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:31:59

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 17:26

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:31:59

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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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 18:24

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:31:59

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

22 SEP 2020 17:23

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**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

16 SEP 2020 14:21

PC Open Date & Time

16 SEP 2020 14:04

PC Close Date & Time

16 SEP 2020 16:34

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**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

16 SEP 2020 18:06

PC Open Date & Time

16 SEP 2020 17:29

PC Close Date & Time

17 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**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

17 SEP 2020 18:34

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:31:59

**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

18 SEP 2020 18:41

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59



US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**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

19 SEP 2020 19:35

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**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

20 SEP 2020 17:27

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**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

21 SEP 2020 18:24

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**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

22 SEP 2020 17:24

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**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 ☐

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 16 SEP 2020 14:22 |
| PC Open Date & Time  | 16 SEP 2020 14:04 |
| PC Close Date & Time | 16 SEP 2020 16:34 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**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 ☐

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 16 SEP 2020 18:08 |
| PC Open Date & Time  | 16 SEP 2020 17:29 |
| PC Close Date & Time | 17 SEP 2020 11:59 |



US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**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 ☒

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 17 SEP 2020 18:34 |
| PC Open Date & Time          | 17 SEP 2020 12:00 |
| PC Close Date & Time         | 18 SEP 2020 11:59 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

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 ☒

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 18 SEP 2020 18:41 |
| PC Open Date & Time          | 18 SEP 2020 12:00 |
| PC Close Date & Time         | 19 SEP 2020 11:59 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**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 ☒

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 19 SEP 2020 19:36 |
| PC Open Date & Time          | 19 SEP 2020 12:00 |
| PC Close Date & Time         | 20 SEP 2020 11:59 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

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 ☒

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 20 SEP 2020 17:27 |
| PC Open Date & Time          | 20 SEP 2020 12:00 |
| PC Close Date & Time         | 21 SEP 2020 11:59 |



US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**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 ☒

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 21 SEP 2020 18:24 |
| PC Open Date & Time          | 21 SEP 2020 12:00 |
| PC Close Date & Time         | 22 SEP 2020 11:59 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**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 ☒

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 22 SEP 2020 17:24 |
| PC Open Date & Time          | 22 SEP 2020 12:00 |
| PC Close Date & Time         | 23 SEP 2020 11:59 |

US3462255

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:59

Was Contact Attempted?

Yes ☒

No ☐

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

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462255

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:59

Was Contact Attempted?

Yes ☒

No ☐

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

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462255

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3462255

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:59

Was Contact Attempted?

Yes ☒

No ☐

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

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462255

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:59

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 14 OCT 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | VISIT3                                  |

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:59

|                                           |                                     |
|-------------------------------------------|-------------------------------------|
| Were vital signs assessed?                | Yes <input type="radio"/>           |
|                                           | No <input checked="" 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            |                                     |
| Height (derived)                          |                                     |
| Weight (derived)                          |                                     |

US3462255

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:59

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.*

US3462255

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

13:40 (24 HR)

Collection date and time (derived)

14 OCT 2020 13:40

US3462255

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| TIMEPOINT                                                                                                                                                                       | DAY 64                                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input checked="" type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input checked="" type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                                |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input checked="" type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission                                                                                                                                                     | 19 OCT 2020 08:10:24                                                                                           |
| Patient Cloud Open Date & Time                                                                                                                                                  | 19 OCT 2020 00:01                                                                                              |
| Patient Cloud Close Date & Time                                                                                                                                                 | 23 OCT 2020 23:59                                                                                              |



US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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

28 OCT 2020 12:02:17

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3462255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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

02 NOV 2020 03:44:56

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2020 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2020 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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



US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

|                                                                                                                                                                                 |                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                                                                                                | 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 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                                                                                                                                                     | 23 NOV 2020 14:53:45                                             |
| Patient Cloud Open Date & Time                                                                                                                                                  | 20 NOV 2020 00:01                                                |
| Patient Cloud Close Date & Time                                                                                                                                                 | 24 NOV 2020 23:59                                                |

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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 ☐ 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 ☐



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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 ☐ 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 ☐

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

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**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

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**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| TIMEPOINT                                                                                                                                                                       | DAY 306                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



US3462255

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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 ☐ 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 ☐

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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 ☐ 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 ☐



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

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

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

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**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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 ☐ 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 ☐

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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 ☐ 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 ☐

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| TIMEPOINT                                                                                                                                                                       | DAY 495                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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 ☐



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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 ☐

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

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 ☐

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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 ☐

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

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08 MAR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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 ☐

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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 ☐



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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 ☐

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| TIMEPOINT                                                                                                                                                                       | DAY 607                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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 ☐ 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 ☐

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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 ☐

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**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 ☐

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| TIMEPOINT                                                                                                                                                                       | DAY 677                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:59

| 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"/>                                               |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

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

US3462255

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462255

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462255

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

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*



US3462255

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

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3462255

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:31:59

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

US3462255

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

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

**Generated On: 26 Nov 2020 09:31:59**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3462255

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:31:59

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:59

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US093-2020-MRNA-1273-P30<br>1000008                                                                                                                          |
| Adverse event                                                  | DEHYDRATION                                                                                                                                                      |
| Was this a medically-attended AE?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 16 OCT 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       | 08:00 (24 HR)                                                                                                                                                    |
| AE start date and time (derived)                               | 16 OCT 2020 08:00                                                                                                                                                |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 17 OCT 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         | 12:00 (24 HR)                                                                                                                                                    |
| AE End Date and Time (derived)                                 | 17 OCT 2020 12:00                                                                                                                                                |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input checked="" type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | True                                                                                                                                                             |
| Hospital Admission Date (dd MMM yyyy)                          | 16 OCT 2020                                                                                                                                                      |
| Hospital Discharge Date (dd MMM yyyy)                          | 17 OCT 2020                                                                                                                                                      |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/><br>Unknown <input type="radio"/>                                                                |
| Number of Days in ICU                                          |                                                                                                                                                                  |

v6.020 DTW (1102)

348 of 2009

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:59

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

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:59

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57 YEAR OLD FEMALE WITH  
HYPERTENSION, TYPE II  
DIABETES, GERD, AND  
HISTORY OF GASTRIC BYPASS  
SURGERY ON 02OCT2020.  
SUBJECT WOKE UP 16OCT2020  
WITH INCREASED FATIGUE  
AND MALAISE. THOSE  
SYMPTOMS HAD BEEN  
ONGOING FOR  
APPROXIMATELY ONE WEEK  
PRIOR, BUT SUDDENLY  
WORSENER. SUBJECT WENT TO  
EMERGENCY DEPARTMENT  
MORNING OF 16OCT2020 AT  
APPROXIMATELY 09:30 AND  
WAS DIAGNOSED WITH  
SEVERE DEHYDRATION AND  
ANEMIA. SUBJECT WAS  
TREATED WITH IV FLUIDS AND  
IRON SUPPLEMENTATION.  
SUBJECT WAS ADMITTED TO  
MONITOR KIDNEY FUNCTION.  
SYMPTOMS IMPROVED WITH  
TREATMENTS. SUBJECT WAS  
DISCHARGED 17OCT2020 AT  
APPROXIMATELY 12:00 WITH  
INSTRUCTIONS TO TAKE OVER  
THE COUNTER IRON  
SUPPLEMENTATION.

---

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

---

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:59

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US093-2020-MRNA-1273-P30<br>1000008                                                                                                                          |
| Adverse event                                                  | ANEMIA                                                                                                                                                           |
| Was this a medically-attended AE?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 16 OCT 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       | 08:00 (24 HR)                                                                                                                                                    |
| AE start date and time (derived)                               | 16 OCT 2020 08:00                                                                                                                                                |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 17 OCT 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         | 12:00 (24 HR)                                                                                                                                                    |
| AE End Date and Time (derived)                                 | 17 OCT 2020 12:00                                                                                                                                                |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input checked="" type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | True                                                                                                                                                             |
| Hospital Admission Date (dd MMM yyyy)                          | 16 OCT 2020                                                                                                                                                      |
| Hospital Discharge Date (dd MMM yyyy)                          | 17 OCT 2020                                                                                                                                                      |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/><br>Unknown <input type="radio"/>                                                                |
| Number of Days in ICU                                          |                                                                                                                                                                  |

v6.020 DTW (1102)

351 of 2009



US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:59

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

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:59

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57 YEAR OLD FEMALE WITH  
HYPERTENSION, TYPE II  
DIABETES, GERD, AND  
HISTORY OF GASTRIC BYPASS  
SURGERY ON 02OCT2020.  
SUBJECT WOKE UP 16OCT2020  
WITH INCREASED FATIGUE  
AND MALAISE. THOSE  
SYMPTOMS HAD BEEN  
ONGOING FOR  
APPROXIMATELY ONE WEEK  
PRIOR, BUT SUDDENLY  
WORSENER. SUBJECT WENT TO  
EMERGENCY DEPARTMENT  
MORNING OF 16OCT2020 AT  
APPROXIMATELY 09:30 AND  
WAS DIAGNOSED WITH  
SEVERE DEHYDRATION AND  
ANEMIA. SUBJECT WAS  
TREATED WITH IV FLUIDS AND  
IRON SUPPLEMENTATION.  
SUBJECT WAS ADMITTED TO  
MONITOR KIDNEY FUNCTION.  
SYMPTOMS IMPROVED WITH  
TREATMENTS. SUBJECT WAS  
DISCHARGED 17OCT2020 AT  
APPROXIMATELY 12:00 WITH  
INSTRUCTIONS TO TAKE OVER  
THE COUNTER IRON  
SUPPLEMENTATION.

---

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

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US3462255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:59

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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:59

|                                                                                       |                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>                                                                                                  |
| Other action taken (check all that apply)                                             |                                                                                                                                                                                                                                                                                 |
| None                                                                                  | False                                                                                                                                                                                                                                                                           |
| Concomitant Medication                                                                | True                                                                                                                                                                                                                                                                            |
| Concomitant Procedure                                                                 | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                               | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input checked="" type="radio"/><br>Recovered/Resolved <input type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:<br>_____ |                                                                                                                                                                                                                                                                                 |
| Narrative<br>_____                                                                    |                                                                                                                                                                                                                                                                                 |
| Serious Adverse Event Derived (CSA Programming Field Only)                            | 0                                                                                                                                                                                                                                                                               |
| Medically Attended AE Derived (CSA Programming Field Only)                            | 0                                                                                                                                                                                                                                                                               |
| Admitted to ICU Derived (CSA Programming Field Only)<br>_____                         |                                                                                                                                                                                                                                                                                 |

US3462255

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

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

**Generated On: 26 Nov 2020 09:31:59**

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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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US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:59

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | HYDROCHLORATHIAZIDE                                                                                                                                                                                                                                                                                                                                                                                                      |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HYPERTENSION                                                                                                                                                                                                                                                                                                                                                                                                             |
| Dose per administration        | 12.5                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:59

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN                       | UNK 2000                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:59

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | MELOXICAM                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | OSTEOARTHRITIS                                                                                                                                                                                                                                                                                                                                                                                                           |
| Dose per administration              | 15                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 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 (2)

Generated On: 26 Nov 2020 09:31:59

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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 2019                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | <input type="text"/>     |                                  |
| Interval Dosage Unit Number (derived)                             | <input type="text"/>     |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:59

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | METFORMIN                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | TYPE II DIABETES                                                                                                                                                                                                                                                                                                                                                                                                         |
| Dose per administration              | 2500                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:59

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | METOPROLOL                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | OCCASIONAL TACHYCARDIA                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration              | 25                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:59

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN                       | UNK 2000                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:59

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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 1995                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:59

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | ASPIRIN                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | CARDIAC RISK                                                                                                                                                                                                                                                                                                                                                                                                             |
| Dose per administration              | 81                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN                       | UNK 1995                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:59

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | ATORVASTATIN                                                                                                                                                                                                                                                                                                                                                                                                             |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | HYPERCHOLESTEROLEMIA                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose per administration              | 10                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:59

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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 2010                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:59

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | CYCLOBENZAPRINE                                                                                                                                                                                                                                                                                                                                                                                                          |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | LOWER BACK PAIN                                                                                                                                                                                                                                                                                                                                                                                                          |
| Dose per administration        | 10                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 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 (8)

Generated On: 26 Nov 2020 09:31:59

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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)                                          |                          | 29 JUL 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 (9)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | DULOXETINE                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | ANXIETY                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Dose per administration        | 60                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:59

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN                       | UNK 2000                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:59

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | GABAPENTIN                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | BILATERAL KNEE ARTHRITIS                                                                                                                                                                                                                                                                                                                                                                                                 |
| Dose per administration              | 300                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input checked="" type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |



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Form: Prior/Concomitant Medication and Vaccination (10)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:59

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | ALLERTEC                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | SEASONAL ALLERGIC RHINITIS<br>/ PERENNIAL ALLERGIC<br>RHINITIS                                                                                                                                                                                                                                                                                                                                                           |
| Dose per administration              | 10                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 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"/>                                                                                                                                                                                                                                                                        |

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:59

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Intraocular              | <input type="checkbox"/>         |
|                                                    | Intramuscular            | <input type="checkbox"/>         |
|                                                    | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                    | Intralesional            | <input type="checkbox"/>         |
|                                                    | Intraperitoneal          | <input type="checkbox"/>         |
|                                                    | Nasal                    | <input type="checkbox"/>         |
|                                                    | Vaginal                  | <input type="checkbox"/>         |
|                                                    | Rectal                   | <input type="checkbox"/>         |
|                                                    | Intravenous              | <input type="checkbox"/>         |
|                                                    | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                    | Intravenous Drip         | <input type="checkbox"/>         |
|                                                    | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN                       | UNK 2015                         |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?                                           | Yes                      | <input checked="" type="radio"/> |
|                                                    | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|                                                    | 803                      | <input type="radio"/>            |
|                                                    | 804                      | <input checked="" type="radio"/> |

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:31:59

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | IRON SUPPLEMENT                                                                                                                                                                                                                                                                                                                                                                                                          |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | ANEMIA                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration        | 325                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 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 checked="" 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"/>                                                                                                                                                                                            |

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:31:59

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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 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)                             |                          | 2                                |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:31:59

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | VICODIN (325/5 MG)                                                                                                                                                                                                                                                                                                                                                                                                       |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | POST GASTRIC BYPASS<br>SURGERY PAIN                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose per administration        | 1                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input checked="" 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"/>                                                                                                                                                                                                                                   |



US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:31:59

|                                                    |                                     |                       |
|----------------------------------------------------|-------------------------------------|-----------------------|
|                                                    | Intramuscular                       | <input type="radio"/> |
|                                                    | Respiratory (Inhalation)            | <input type="radio"/> |
|                                                    | Intralesional                       | <input type="radio"/> |
|                                                    | Intraperitoneal                     | <input type="radio"/> |
|                                                    | Nasal                               | <input type="radio"/> |
|                                                    | Vaginal                             | <input type="radio"/> |
|                                                    | Rectal                              | <input type="radio"/> |
|                                                    | Intravenous                         | <input type="radio"/> |
|                                                    | Intravenous Bolus                   | <input type="radio"/> |
|                                                    | Intravenous Drip                    | <input type="radio"/> |
|                                                    | Other                               | <input type="radio"/> |
| <hr/>                                              |                                     |                       |
| If route of administration is Other, specify _____ |                                     |                       |
| Start date (dd MMM yyyy)                           | 02 OCT 2020                         |                       |
| Start date completely unknown                      | False                               |                       |
| Ongoing?                                           | Yes <input type="radio"/>           |                       |
|                                                    | No <input checked="" type="radio"/> |                       |
| <hr/>                                              |                                     |                       |
| If not Ongoing, End date (dd MMM yyyy)             |                                     | 03 OCT 2020           |
| Was this medication taken for solicited event?     | Yes <input type="radio"/>           |                       |
|                                                    | No <input checked="" type="radio"/> |                       |
| <hr/>                                              |                                     |                       |
| Separate Dosage Number (derived)                   | _____                               |                       |
| Interval Dosage Unit Number (derived)              | _____                               |                       |
| Interval Dosage Definition (derived)               | 802 <input type="radio"/>           |                       |
|                                                    | 803 <input type="radio"/>           |                       |
|                                                    | 804 <input type="radio"/>           |                       |

US3462255

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 09:31:59**

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

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

---

US3462255

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures**

**Generated On: 26 Nov 2020 09:31:59**

| Procedure/Surgery date ( <i>dd MMM<br/>yyyy</i> ) | Procedure/Surgery      | Indication      | If indication is Other, specify |
|---------------------------------------------------|------------------------|-----------------|---------------------------------|
| 02 OCT 2020                                       | GASTRIC BYPASS SURGERY | Medical History |                                 |

US3462255

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:31:59

---

Date of dosing discontinuation (dd MMM yyyy)

---

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

---

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

---

US3462255

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:31:59

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 ☐

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:59

|                                                                |                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                          | USA-US093-2020-MRNA-1273-P301000008                              |
| Serious                                                        | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death                                                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                      | EDWARD                                                           |
| Investigator's Last Name                                       | KERWIN                                                           |
| Site Address: Street                                           |                                                                  |
| Site Address: City                                             |                                                                  |
| Site Address: State                                            |                                                                  |
| Site Address: Postal Code                                      |                                                                  |
| Investigator Country                                           | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                             | 2                                                                |

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:31:59

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US093-2020-MRNA-1273-P301000008                              |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | EDWARD                                                           |
| Investigator's Last Name                                                                                                                                                                      | KERWIN                                                           |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 2                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 21/OCT/2020 21:07                                                |
| 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                                                             |

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:31:59

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US093-2020-MRNA-1273-P301000008                              |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | EDWARD                                                           |
| Investigator's Last Name                                                                                                                                                                      | KERWIN                                                           |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 2                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 06/NOV/2020 19:07                                                |
| 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

US3462255 (Prod: Crisor, LLC)

US3462255

**Form: Participant Creation**

**Generated On: 26 Nov 2020 09:31:59**

[Participant ID](#)

| Audit                    | User                                           | Time (GMT)           |
|--------------------------|------------------------------------------------|----------------------|
| User entered 'US3462255' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 19 Aug 2020 20:44:28 |

US3462255

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:31:59**

[Was this visit performed?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:52:23 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                                           | Time (GMT)           |
|----------------------------|------------------------------------------------|----------------------|
| User entered '19 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 19 Aug 2020 20:44:29 |

US3462255

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| User entered 'Clinic (Clinic)' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:52:23 |
|                                |                       |                      |
|                                |                       |                      |

US3462255

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:31:59**

[Folder OID](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 19 Aug 2020 21:52:23 |

US3462255

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                                           | Time (GMT)           |
|----------------------------|------------------------------------------------|----------------------|
| User entered (b) (6) 1962' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 19 Aug 2020 20:44:30 |

US3462255

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:31:59**

[Age](#)

| Audit             | User                  | Time (GMT)           |
|-------------------|-----------------------|----------------------|
| User entered '57' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:52:45 |
|                   |                       |                      |
|                   |                       |                      |



US3462255

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:31:59**

[Age Units](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 19 Aug 2020 21:52:45 |

US3462255

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:31:59**

[Age \(Derived\)](#)

| Audit             | User   | Time (GMT)           |
|-------------------|--------|----------------------|
| User entered '57' | System | 19 Aug 2020 21:53:11 |

US3462255

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:31:59**

[Sex](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User entered 'Female (F)' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:52:45 |
|                           |                       |                      |
|                           |                       |                      |

US3462255

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:31:59**

[Ethnicity](#)

| Audit                                                          | User                                              | Time (GMT)           |
|----------------------------------------------------------------|---------------------------------------------------|----------------------|
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Danuel Hamlin (b) (4)<br>[REDACTED]<br>[REDACTED] | 19 Aug 2020 21:52:45 |

US3462255

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:59

White

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '1' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:52:45 |
|                  |                       |                      |
|                  |                       |                      |

US3462255

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:31:59**

[Black](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:52:45 |
|                  |                       |                      |
|                  |                       |                      |

US3462255

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:31:59**

[Asian](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:52:45 |
|                  |                       |                      |
|                  |                       |                      |

US3462255

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:31:59**

[American Indian or Alaska Native](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:52:45 |
|                  |                       |                      |
|                  |                       |                      |



US3462255

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:31:59**

[Native Hawaiian or other Pacific Islander](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:52:45 |
|                  |                       |                      |
|                  |                       |                      |

US3462255

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:31:59**

[Other](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:52:45 |
|                  |                       |                      |
|                  |                       |                      |

US3462255

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:31:59**

[If race is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 19 Aug 2020 21:52:45 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:31:59**

[Unknown](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:52:45 |
|                  |                       |                      |
|                  |                       |                      |

US3462255

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:31:59**

[Not reported](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:52:45 |
|                  |                       |                      |
|                  |                       |                      |

US3462255

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered '19 Aug 2020' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:53:11 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Aug 2020' | System | 19 Aug 2020 21:53:11 |

US3462255

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 19 Aug 2020 21:53:11 |



US3462255

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:31:59**

[Protocol Version](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| User entered 'Amendment 2 (2)' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:53:11 |
|                                |                       |                      |
|                                |                       |                      |

US3462255

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:53:11 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 19 Aug 2020 21:53:11 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:31:59**

If reason for screen fail is Other, specify

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 19 Aug 2020 21:53:11 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:31:59**

[Was this participant screened previously?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:53:11 |
|                       |                       |                      |
|                       |                       |                      |

US3462255

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:31:59**

[If Yes, previous participant number](#)

| Audit               | User                                           | Time (GMT)           |
|---------------------|------------------------------------------------|----------------------|
| User entered empty. | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 19 Aug 2020 20:44:29 |

US3462255

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:31:59**

[Enrollment Trigger](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Aug 2020 21:53:20 |

US3462255

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:53:20 |
|                        |                       |                      |
|                        |                       |                      |



US3462255

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 09:31:59**

[Were any significant conditions reported?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:03:31 |

US3462255

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:59

[Condition](#)

| Audit                                                                                                                                                                                                                                                     | User                            | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0. | Coder Import (b) (4)<br>(b) (4) | 20 Aug 2020 21:48:24 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                                                                                    | Coder Import (b) (4)<br>(b) (4) | 20 Aug 2020 21:48:24 |
| Data point term sent to Coder                                                                                                                                                                                                                             | System                          | 20 Aug 2020 19:04:38 |
| User entered 'Diabetes mellitus (type 2)'                                                                                                                                                                                                                 | (b) (4), (b) (6)<br>(b) (4)     | 20 Aug 2020 19:04:11 |

US3462255

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2011' | (b) (4), (b) (6) | 20 Aug 2020 19:04:11 |

US3462255

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:04:11 |

US3462255

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:04:11 |

US3462255

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:04:11 |

US3462255

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:04:11 |

US3462255

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2011' | System | 20 Aug 2020 19:04:11 |



US3462255

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2011' | System | 20 Aug 2020 19:04:11 |

US3462255

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:04:11 |

US3462255

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:04:11 |

US3462255

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:59

[Condition](#)

| Audit                                                                                                                                                                                 | User                             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\23.0. | Coder Import (b) (4)<br>(b) (4)  | 21 Oct 2020 00:28:23 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                           | Coder Import (b) (4)<br>(b) (4)  | 21 Oct 2020 00:28:23 |
| Data point term sent to Coder                                                                                                                                                         | System                           | 21 Oct 2020 00:27:17 |
| User closed query 'DM-Coding: Please expand the reported abbreviations, entering the full text as the reported term.' (Site from System).                                             | System                           | 21 Oct 2020 00:26:54 |
| Query 'DM-Coding: Please expand the reported abbreviations, entering the full text as the reported term.' answered with 'Corrected' (Site from System).                               | Danuel Hamlin (b) (4)<br>(b) (4) | 21 Oct 2020 00:26:54 |
| User entered 'Seasonal Allergic Rhinitis / Perennial Allergic Rhinitis' reason for change: Data Entry Error                                                                           | Danuel Hamlin (b) (4)<br>(b) (4) | 21 Oct 2020 00:26:49 |
| User opened query 'DM-Coding: Please expand the reported abbreviations, entering the full text as the reported term.' (Site from System).                                             | Coder Import (b) (4)<br>(b) (4)  | 14 Oct 2020 12:47:27 |
| Data point term sent to Coder                                                                                                                                                         | System                           | 20 Aug 2020 19:04:39 |
| User entered 'SAR/PAR'                                                                                                                                                                | (b) (4), (b) (6)<br>(b) (4)      | 20 Aug 2020 19:04:30 |

US3462255

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 1980' | (b) (4), (b) (6) | 20 Aug 2020 19:04:30 |

US3462255

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:04:30 |

US3462255

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:04:30 |

US3462255

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:04:30 |



US3462255

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:04:30 |

US3462255

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1980' | System | 20 Aug 2020 19:04:30 |

US3462255

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1980' | System | 20 Aug 2020 19:04:30 |

US3462255

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:04:30 |

US3462255

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:04:30 |

US3462255

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:59

[Condition](#)

| Audit                                                                                                                                                                                        | User                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0. | Coder Import (b) (4) | 20 Aug 2020 19:06:29 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                  | Coder Import (b) (4) | 20 Aug 2020 19:06:29 |
| Data point term sent to Coder                                                                                                                                                                | System               | 20 Aug 2020 19:05:40 |
| User entered 'hypertension'                                                                                                                                                                  | (b) (4), (b) (6)     | 20 Aug 2020 19:04:49 |

US3462255

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 1995' | (b) (4), (b) (6) | 20 Aug 2020 19:04:49 |

US3462255

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:04:49 |



US3462255

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:04:49 |

US3462255

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:04:49 |

US3462255

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:31:59**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:04:49 |

US3462255

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1995' | System | 20 Aug 2020 19:04:49 |

US3462255

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1995' | System | 20 Aug 2020 19:04:49 |

US3462255

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:04:49 |

US3462255

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:04:49 |

US3462255

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:31:59

[Condition](#)

| Audit                                                                                                                                                                    | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\23.0. | Coder Import (b) (4)  | 24 Nov 2020 09:11:11 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                   | Coder Import (b) (4)  | 24 Nov 2020 09:11:11 |
| Data point term sent to Coder                                                                                                                                            | System                | 06 Nov 2020 00:23:44 |
| Coding entries removed.                                                                                                                                                  | Danuel Hamlin (b) (4) | 06 Nov 2020 00:22:53 |
|                                                                                                                                                                          |                       |                      |
| User entered 'OCCASIONAL TACHYCARDIA' reason for change: Data Entry Error                                                                                                | Danuel Hamlin (b) (4) | 06 Nov 2020 00:22:53 |
|                                                                                                                                                                          |                       |                      |
| User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\23.0. | Coder Import (b) (4)  | 21 Aug 2020 09:36:12 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                   | Coder Import (b) (4)  | 21 Aug 2020 09:36:12 |
| Data point term sent to Coder                                                                                                                                            | System                | 20 Aug 2020 19:05:41 |
| User entered 'tachycardia (intermittent)'                                                                                                                                | (b) (4), (b) (6)      | 20 Aug 2020 19:05:31 |
|                                                                                                                                                                          |                       |                      |



US3462255

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2000' | (b) (4), (b) (6) | 20 Aug 2020 19:05:31 |

US3462255

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:05:31 |

US3462255

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:05:31 |

US3462255

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:05:31 |

US3462255

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:31:59**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:05:31 |

US3462255

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 20 Aug 2020 19:05:31 |

US3462255

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 20 Aug 2020 19:05:31 |

US3462255

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:05:31 |



US3462255

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:05:31 |

US3462255

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:31:59

[Condition](#)

| Audit                                                                                                                                                                                                                                                                               | User                                        | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\23.0. | Coder Import (b) (4)<br>(b) (4)             | 06 Nov 2020 00:24:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                         | Coder Import (b) (4)<br>(b) (4)             | 06 Nov 2020 00:24:24 |
| Data point term sent to Coder                                                                                                                                                                                                                                                       | System                                      | 06 Nov 2020 00:23:44 |
| Coding entries removed.                                                                                                                                                                                                                                                             | Danuel Hamlin (b) (4)<br>(b) (4)<br>(b) (4) | 06 Nov 2020 00:23:19 |
| User entered 'GASTROESOPHOGEAL REFLUX DISEASE' reason for change: Data Entry Error                                                                                                                                                                                                  | Danuel Hamlin (b) (4)<br>(b) (4)<br>(b) (4) | 06 Nov 2020 00:23:19 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\23.0.                            | Coder Import (b) (4)<br>(b) (4)             | 20 Aug 2020 19:07:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                         | Coder Import (b) (4)<br>(b) (4)             | 20 Aug 2020 19:07:20 |
| Data point term sent to Coder                                                                                                                                                                                                                                                       | System                                      | 20 Aug 2020 19:06:42 |
| User entered 'GERD'                                                                                                                                                                                                                                                                 | (b) (4), (b) (6)<br>(b) (4)                 | 20 Aug 2020 19:05:59 |

US3462255

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 1995' | (b) (4), (b) (6) | 20 Aug 2020 19:05:59 |

US3462255

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:05:59 |

US3462255

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:05:59 |

US3462255

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:05:59 |

US3462255

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:31:59**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:05:59 |

US3462255

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1995' | System | 20 Aug 2020 19:05:59 |



US3462255

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1995' | System | 20 Aug 2020 19:05:59 |

US3462255

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:05:59 |

US3462255

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:05:59 |

US3462255

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:31:59

[Condition](#)

| Audit                                                                                                                                                                                                       | User                 | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Aug 2020 19:13:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                | Coder Import (b) (4) | 20 Aug 2020 19:13:20 |
| Data point term sent to Coder                                                                                                                                                                               | System               | 20 Aug 2020 19:11:53 |
| User entered 'hypercholesterolemia'                                                                                                                                                                         | (b) (4), (b) (6)     | 20 Aug 2020 19:11:04 |

US3462255

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2010' | (b) (4), (b) (6) | 20 Aug 2020 19:11:04 |

US3462255

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:11:04 |

US3462255

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:11:04 |

US3462255

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:11:04 |



US3462255

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:31:59**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:11:04 |

US3462255

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 20 Aug 2020 19:11:04 |

US3462255

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2010' | System | 20 Aug 2020 19:11:04 |

US3462255

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:11:04 |

US3462255

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:11:04 |

US3462255

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:31:59

[Condition](#)

| Audit                                                                                                                                                                                                | User                 | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Aug 2020 19:13:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                         | Coder Import (b) (4) | 20 Aug 2020 19:13:20 |
| Data point term sent to Coder                                                                                                                                                                        | System               | 20 Aug 2020 19:11:55 |
| User entered 'osteoarthritis (bilateral knees)'                                                                                                                                                      | (b) (4), (b) (6)     | 20 Aug 2020 19:11:32 |

US3462255

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2005' | (b) (4), (b) (6) | 20 Aug 2020 19:11:32 |

US3462255

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:11:32 |



US3462255

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:11:32 |

US3462255

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:11:32 |

US3462255

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:31:59**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:11:32 |

US3462255

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2005' | System | 20 Aug 2020 19:11:32 |

US3462255

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2005' | System | 20 Aug 2020 19:11:32 |

US3462255

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:11:32 |

US3462255

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:11:32 |

US3462255

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:31:59

[Condition](#)

| Audit                                                                                                                                                                                        | User                                        | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|
| User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\23.0. | Coder Import (b) (4)<br>(b) (4)             | 06 Nov 2020 00:41:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                  | Coder Import (b) (4)<br>(b) (4)             | 06 Nov 2020 00:41:24 |
| Data point term sent to Coder                                                                                                                                                                | System                                      | 06 Nov 2020 00:24:45 |
| Coding entries removed.                                                                                                                                                                      | Danuel Hamlin (b) (4)<br>(b) (4)<br>(b) (4) | 06 Nov 2020 00:24:06 |
| User entered 'BILATERAL CARPEL TUNNEL' reason for change: Data Entry Error                                                                                                                   | Danuel Hamlin (b) (4)<br>(b) (4)            | 06 Nov 2020 00:24:06 |
| User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\23.0. | Coder Import (b) (4)<br>(b) (4)             | 20 Aug 2020 19:13:21 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                  | Coder Import (b) (4)<br>(b) (4)             | 20 Aug 2020 19:13:21 |
| Data point term sent to Coder                                                                                                                                                                | System                                      | 20 Aug 2020 19:12:56 |
| User entered 'carpel tunnel syndrome'                                                                                                                                                        | (b) (4), (b) (6)<br>(b) (4)                 | 20 Aug 2020 19:11:59 |



US3462255

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 1985' | (b) (4), (b) (6) | 20 Aug 2020 19:11:59 |

US3462255

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:11:59 |

US3462255

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition ongoing at study entry](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:11:59 |

US3462255

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 1988' | (b) (4), (b) (6) | 20 Aug 2020 19:11:59 |

US3462255

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:31:59**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:11:59 |

US3462255

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1985' | System | 20 Aug 2020 19:11:59 |

US3462255

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1985' | System | 20 Aug 2020 19:11:59 |

US3462255

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1988' | System | 20 Aug 2020 19:11:59 |



US3462255

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1988' | System | 20 Aug 2020 19:11:59 |

US3462255

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:31:59

[Condition](#)

| Audit                                                                                                                                                                                                         | User                                        | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear - version MedDRA\23.0. | Coder Import (b) (4)<br>(b) (4)             | 11 Nov 2020 10:10:48 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                                        | Coder Import (b) (4)<br>(b) (4)             | 11 Nov 2020 10:10:48 |
| Data point term sent to Coder                                                                                                                                                                                 | System                                      | 06 Nov 2020 00:24:45 |
| Coding entries removed.                                                                                                                                                                                       | Danuel Hamlin (b) (4)<br>(b) (4)<br>(b) (4) | 06 Nov 2020 00:24:38 |
| User entered 'TORN RIGHT LATERAL MENISCUS' reason for change: Data Entry Error                                                                                                                                | Danuel Hamlin (b) (4)<br>(b) (4)            | 06 Nov 2020 00:24:38 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear - version MedDRA\23.0. | Coder Import (b) (4)<br>(b) (4)             | 20 Aug 2020 19:13:21 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                   | Coder Import (b) (4)<br>(b) (4)             | 20 Aug 2020 19:13:21 |
| Data point term sent to Coder                                                                                                                                                                                 | System                                      | 20 Aug 2020 19:13:00 |
| User entered 'meniscus tear'                                                                                                                                                                                  | (b) (4), (b) (6)<br>(b) (4)                 | 20 Aug 2020 19:12:54 |

US3462255

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2008' | (b) (4), (b) (6) | 20 Aug 2020 19:12:54 |

US3462255

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:12:54 |

US3462255

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition ongoing at study entry](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:12:54 |

US3462255

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2009' | (b) (4), (b) (6) | 20 Aug 2020 19:12:54 |

US3462255

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:31:59**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:12:54 |

US3462255

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2008' | System | 20 Aug 2020 19:12:54 |



US3462255

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2008' | System | 20 Aug 2020 19:12:54 |

US3462255

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2009' | System | 20 Aug 2020 19:12:54 |

US3462255

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2009' | System | 20 Aug 2020 19:12:54 |

US3462255

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:31:59

[Condition](#)

| Audit                                                                                                                                                               | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Aug 2020 19:15:26 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                        | Coder Import (b) (4) | 20 Aug 2020 19:15:26 |
| Data point term sent to Coder                                                                                                                                       | System               | 20 Aug 2020 19:14:01 |
| User entered 'anxiety'                                                                                                                                              | (b) (4), (b) (6)     | 20 Aug 2020 19:13:17 |

US3462255

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'un UNK 2000' | (b) (4), (b) (6) | 20 Aug 2020 19:13:17 |

US3462255

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:13:17 |

US3462255

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition ongoing at study entry](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:13:17 |
|                        |                  |                      |

US3462255

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:13:17 |



US3462255

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:31:59**

[Stop date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:13:17 |

US3462255

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 20 Aug 2020 19:13:17 |

US3462255

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 20 Aug 2020 19:13:17 |

US3462255

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:13:17 |

US3462255

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:13:17 |

US3462255

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:31:59

[Condition](#)

| Audit                                                                                                                                                                                                         | User                                        | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)             | 21 Oct 2020 05:04:27 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                       | Coder Import (b) (4)<br>(b) (4)             | 21 Oct 2020 05:04:27 |
| Data point term sent to Coder                                                                                                                                                                                 | System                                      | 21 Oct 2020 00:28:18 |
| User entered 'Mild Obestiy'                                                                                                                                                                                   | Danuel Hamlin (b) (4)<br>(b) (4)<br>(b) (4) | 21 Oct 2020 00:27:51 |

US3462255

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered 'un UNK 2010' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:27:51 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:27:51 |
|                  |                       |                      |
|                  |                       |                      |



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**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition ongoing at study entry](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:27:51 |
|                        |                       |                      |
|                        |                       |                      |

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**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:27:51 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:31:59**

[Stop date completely unknown](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:27:51 |
|                  |                       |                      |
|                  |                       |                      |

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**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 21 Oct 2020 00:27:51 |

US3462255

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2010' | System | 21 Oct 2020 00:27:51 |

US3462255

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Oct 2020 00:27:51 |

US3462255

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Oct 2020 00:27:51 |

US3462255

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:31:59

[Condition](#)

| Audit                                                                                                                                                                                                                                                               | User                                        | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)             | 06 Nov 2020 00:27:27 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                                                        | Coder Import (b) (4)<br>(b) (4)             | 06 Nov 2020 00:27:27 |
| Data point term sent to Coder                                                                                                                                                                                                                                       | System                                      | 06 Nov 2020 00:26:46 |
| User entered 'LOWER BACK PAIN'                                                                                                                                                                                                                                      | Danuel Hamlin (b) (4)<br>(b) (4)<br>(b) (4) | 06 Nov 2020 00:25:57 |



US3462255

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered 'UN Jul 2020' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:25:57 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:25:57 |
|                  |                       |                      |
|                  |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition ongoing at study entry](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:25:57 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 00:25:57 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:31:59**

[Stop date completely unknown](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:25:57 |
|                  |                       |                      |
|                  |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jul 2020' | System | 06 Nov 2020 00:25:57 |

US3462255

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 06 Nov 2020 00:25:57 |

US3462255

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:25:57 |



US3462255

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:25:57 |

US3462255

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:31:59

[Condition](#)

| Audit                                                                                                                                                                                                                                 | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0. | Coder Import (b) (4)  | 06 Nov 2020 00:33:34 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                          | Coder Import (b) (4)  | 06 Nov 2020 00:33:34 |
| Data point term sent to Coder                                                                                                                                                                                                         | System                | 06 Nov 2020 00:32:54 |
| User entered 'Cesarean Section'                                                                                                                                                                                                       | Danuel Hamlin (b) (4) | 06 Nov 2020 00:32:11 |
|                                                                                                                                                                                                                                       |                       |                      |
|                                                                                                                                                                                                                                       |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered 'un UNK 1982' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:32:11 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:32:11 |
|                  |                       |                      |
|                  |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition ongoing at study entry](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:32:11 |
|                       |                       |                      |
|                       |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered 'un UNK 1982' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:32:11 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Stop date completely unknown](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:32:11 |
|                  |                       |                      |
|                  |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1982' | System | 06 Nov 2020 00:32:11 |



US3462255

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1982' | System | 06 Nov 2020 00:32:11 |

US3462255

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1982' | System | 06 Nov 2020 00:32:11 |

US3462255

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1982' | System | 06 Nov 2020 00:32:11 |

US3462255

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:31:59

[Condition](#)

| Audit                                                                                                                                                                                                                                 | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0. | Coder Import (b) (4)  | 06 Nov 2020 00:49:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                          | Coder Import (b) (4)  | 06 Nov 2020 00:49:24 |
| Data point term sent to Coder                                                                                                                                                                                                         | System                | 06 Nov 2020 00:32:54 |
| User entered 'CESAREAN SECTION'                                                                                                                                                                                                       | Danuel Hamlin (b) (4) | 06 Nov 2020 00:32:38 |
|                                                                                                                                                                                                                                       |                       |                      |
|                                                                                                                                                                                                                                       |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered 'un UNK 1988' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:32:38 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:32:38 |
|                  |                       |                      |
|                  |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition ongoing at study entry](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:32:38 |
|                       |                       |                      |
|                       |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered 'un UNK 1988' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:32:38 |
|                            |                       |                      |
|                            |                       |                      |



US3462255

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Stop date completely unknown](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:32:38 |
|                  |                       |                      |
|                  |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1988' | System | 06 Nov 2020 00:32:38 |

US3462255

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1988' | System | 06 Nov 2020 00:32:38 |

US3462255

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1988' | System | 06 Nov 2020 00:32:38 |

US3462255

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1988' | System | 06 Nov 2020 00:32:38 |

US3462255

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:31:59

[Condition](#)

| Audit                                                                                                                                                                                                                                                         | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\23.0. | Coder Import (b) (4)  | 06 Nov 2020 00:50:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                   | Coder Import (b) (4)  | 06 Nov 2020 00:50:24 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\23.0. | Coder Import (b) (4)  | 06 Nov 2020 00:34:28 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                   | Coder Import (b) (4)  | 06 Nov 2020 00:34:28 |
| Data point term sent to Coder                                                                                                                                                                                                                                 | System                | 06 Nov 2020 00:33:55 |
| User entered 'Bilateral Carpel Tunnel Repair'                                                                                                                                                                                                                 | Danuel Hamlin (b) (4) | 06 Nov 2020 00:33:12 |
|                                                                                                                                                                                                                                                               |                       |                      |
|                                                                                                                                                                                                                                                               |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered 'un UNK 1988' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:33:12 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:33:12 |
|                  |                       |                      |
|                  |                       |                      |



US3462255

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition ongoing at study entry](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:33:12 |
|                       |                       |                      |
|                       |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered 'un UNK 1988' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:33:12 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:31:59**

[Stop date completely unknown](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:33:12 |
|                  |                       |                      |
|                  |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1988' | System | 06 Nov 2020 00:33:12 |

US3462255

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1988' | System | 06 Nov 2020 00:33:12 |

US3462255

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1988' | System | 06 Nov 2020 00:33:12 |

US3462255

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1988' | System | 06 Nov 2020 00:33:12 |

US3462255

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition](#)

| Audit                                                                                                                                                                                                                  | User                                        | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Meniscus operation, LLT: Meniscus operation - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)             | 06 Nov 2020 00:36:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                           | Coder Import (b) (4)<br>(b) (4)             | 06 Nov 2020 00:36:24 |
| Data point term sent to Coder                                                                                                                                                                                          | System                                      | 06 Nov 2020 00:35:56 |
| User entered 'Right Lateral Meniscus Repair'                                                                                                                                                                           | Danuel Hamlin (b) (4)<br>(b) (4)<br>(b) (4) | 06 Nov 2020 00:35:27 |



US3462255

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered 'un UNK 2009' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:35:27 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:35:27 |
|                  |                       |                      |
|                  |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:31:59**

[Condition ongoing at study entry](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:35:27 |
|                       |                       |                      |
|                       |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered 'un UNK 2009' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:35:27 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:31:59**

[Stop date completely unknown](#)

| Audit            | User                  | Time (GMT)           |
|------------------|-----------------------|----------------------|
| User entered '0' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:35:27 |
|                  |                       |                      |
|                  |                       |                      |

US3462255

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2009' | System | 06 Nov 2020 00:35:27 |

US3462255

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2009' | System | 06 Nov 2020 00:35:27 |

US3462255

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2009' | System | 06 Nov 2020 00:35:27 |



US3462255

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2009' | System | 06 Nov 2020 00:35:27 |

US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

[Were vital signs assessed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:40:30 |

US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '19 Aug 2020' | (b) (4), (b) (6) | 20 Aug 2020 19:40:30 |

US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| User entered '13:53' | (b) (4), (b) (6) | 20 Aug 2020 19:40:30 |

US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 13:53' | System | 20 Aug 2020 19:40:30 |

US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '165' cm     | (b) (4), (b) (6) | 20 Aug 2020 19:40:30 |
| DataPoint set to visible. | System           | 19 Aug 2020 21:53:20 |

US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '105' kg     | (b) (4), (b) (6) | 20 Aug 2020 19:40:30 |
| DataPoint set to visible. | System           | 19 Aug 2020 21:53:20 |

US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

BMI (xxx.x)

| Audit                                      | User   | Time (GMT)           |
|--------------------------------------------|--------|----------------------|
| Amendment Manager: User entered '38.56749' | System | 17 Sep 2020 00:15:05 |
| User entered '38.6'                        | System | 20 Aug 2020 19:40:30 |
| DataPoint set to visible.                  | System | 19 Aug 2020 21:53:20 |



US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

[BMI units](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered 'kg/m2'      | System | 20 Aug 2020 19:40:30 |
| DataPoint set to visible. | System | 19 Aug 2020 21:53:20 |

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:59

Temperature (xxx.x)

| Audit                                                                       | User             | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 04 Nov 2020 20:13:21 |
| User entered '98.9' F                                                       | (b) (4), (b) (6) | 20 Aug 2020 19:40:30 |

US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

[Route of measurement](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 04 Nov 2020 20:13:21 |
| User entered 'Other (Other)'                           | (b) (4), (b) (6) | 20 Aug 2020 19:40:30 |

US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

[If Other, specify](#)

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 04 Nov 2020 20:13:21 |
| User entered 'tympanic'                                | (b) (4), (b) (6) | 20 Aug 2020 19:40:30 |

US3462255

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:59

[Pulse \(xxx\)](#)

| Audit                                                                       | User             | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 04 Nov 2020 20:13:21 |
| User entered '84'                                                           | (b) (4), (b) (6) | 20 Aug 2020 19:40:30 |

US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 20 Aug 2020 19:40:30 |

US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                               | User             | Time (GMT)           |
|-----------------------------------------------------|------------------|----------------------|
| User entered missing code ND - Not Done; reason for | (b) (4), (b) (6) | 04 Nov 2020 20:13:21 |
| change Data Entry Error                             |                  |                      |
| User entered '16'                                   | (b) (4), (b) (6) | 20 Aug 2020 19:40:30 |
|                                                     |                  |                      |

US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 20 Aug 2020 19:40:30 |



US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                                                       | User             | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 04 Nov 2020 20:13:21 |
| User entered '126'                                                          | (b) (4), (b) (6) | 20 Aug 2020 19:40:30 |

US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Aug 2020 19:40:30 |

US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                                                       | User             | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 04 Nov 2020 20:13:21 |
| User entered '76'                                                           | (b) (4), (b) (6) | 20 Aug 2020 19:40:30 |

US3462255

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Aug 2020 19:40:30 |

US3462255

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:31:59**

[Was the physical examination performed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:40:38 |

US3462255

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:31:59**

[Date of examination \(dd MMM yyyy\)](#)

| Audit                                                                                                                                    | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).    | (b) (4), (b) (6) | 24 Sep 2020 11:23:30 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). |                  | 16 Sep 2020 21:05:41 |
| User entered '19 Aug 2020'                                                                                                               | (b) (4), (b) (6) | 20 Aug 2020 19:40:38 |

US3462255

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:31:59**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '19 Aug 2020' | (b) (4), (b) (6) | 20 Aug 2020 19:41:16 |

US3462255

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:41:16 |



US3462255

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:31:59

If No, what is the reason?

| Audit                                                                                                                                                                                                                                                                                                                              | User                  | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).           | (b) (4), (b) (6)      | 18 Nov 2020 05:42:23 |
| Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'Added' (Site from DM). | Danuel Hamlin (b) (4) | 06 Nov 2020 00:31:00 |
| User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).           | (b) (4), (b) (6)      | 09 Oct 2020 04:22:19 |
| User entered 'Surgically sterile (SURGICALLY STERILE)'                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)      | 20 Aug 2020 19:41:16 |

US3462255

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:31:59**

[If Partner medically sterile or Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:41:16 |

US3462255

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:31:59**

[If Surgically sterile, date of surgery \(dd MMM yyyy\)](#)

| Audit                                                             | User                                | Time (GMT)           |
|-------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'un UNK 1988' reason for change:<br>Data Entry Error | Danuel Hamlin (b) (4)<br>[REDACTED] | 06 Nov 2020 00:30:02 |
| User entered empty.                                               | (b) (4), (b) (6)<br>[REDACTED]      | 20 Aug 2020 19:41:16 |

US3462255

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:31:59**

[Date of surgery unknown](#)

| Audit                                                | User                  | Time (GMT)           |
|------------------------------------------------------|-----------------------|----------------------|
| User entered '0' reason for change: Data Entry Error | Danuel Hamlin (b) (4) | 06 Nov 2020 00:30:02 |
|                                                      |                       |                      |
| User entered '1'                                     | (b) (4), (b) (6)      | 20 Aug 2020 19:41:16 |
|                                                      |                       |                      |

US3462255

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:41:16 |

US3462255

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:31:59**

[Date of last menstruation unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:41:16 |

US3462255

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |



US3462255

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:31:59**

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |



US3462255

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:59

[Other](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:59

[Specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:31:59**

**No Risk Identified**

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

**Folder:** Screening

**Form:** Risk of Exposure

**Generated On:** 26 Nov 2020 09:31:59

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

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:59

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

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |



US3462255

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:31:59**

**Resides in a single family home** (i.e., detached housing)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '1' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:59

[Other](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |
|                  |                  |                      |

US3462255

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:59

[Specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:42:41 |

US3462255

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:31:59**

[Was this visit performed?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:53:40 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered '19 Aug 2020' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:53:40 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:59

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

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| User entered 'Clinic (Clinic)' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:53:40 |
|                                |                       |                      |
|                                |                       |                      |

US3462255

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:31:59**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 19 Aug 2020 21:53:40 |

US3462255

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                                            | Time (GMT)           |
|----------------------------|-------------------------------------------------|----------------------|
| User entered '19 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 19 Aug 2020 20:59:28 |



US3462255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:59

What was the participant's randomization number?

| Audit                                                                                                      | User                                           | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------|------------------------------------------------|----------------------|
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System                                         | 21 Aug 2020 05:43:28 |
| Amendment Manager: Data point set to conformant.                                                           | System                                         | 21 Aug 2020 05:43:28 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).                    | System                                         | 19 Aug 2020 20:59:28 |
| User entered '144306' (non-conformant).                                                                    | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 19 Aug 2020 20:59:28 |

US3462255

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                             | User                                           | Time (GMT)           |
|---------------------------------------------------|------------------------------------------------|----------------------|
| User entered '>=18 and <65 years and at risk (2)' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 19 Aug 2020 20:59:28 |

US3462255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                    | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| 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)      | 16 Nov 2020 16:09:09 |
| Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'Added' (Site from DM). | Danuel Hamlin (b) (4) | 06 Nov 2020 01:10:16 |
| User entered 'No (N)'                                                                                                                                                    | Danuel Hamlin (b) (4) | 06 Nov 2020 01:09:39 |
| 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)      | 01 Sep 2020 14:25:21 |

US3462255

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:09:39 |
|                       |                       |                      |
|                       |                       |                      |

US3462255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:59

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

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:09:39 |
|                       |                       |                      |
|                       |                       |                      |

US3462255

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:31:59**

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:09:39 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:59

[Liver Disease](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:09:39 |
|                       |                       |                      |
|                       |                       |                      |

US3462255

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                        | User                  | Time (GMT)           |
|----------------------------------------------|-----------------------|----------------------|
| User entered 'No (N)'                        | Danuel Hamlin (b) (4) | 06 Nov 2020 01:09:39 |
|                                              |                       |                      |
| Amendment Manager: DataPoint set to visible. | System                | 19 Sep 2020 10:36:21 |
| Amendment Manager inserted this DataPoint.   | System                | 19 Sep 2020 01:38:11 |



US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:59

Height

| Audit                                                                                                                                                                                                     | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).                | (b) (4), (b) (6) | 10 Nov 2020 21:22:10 |
| Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected.' (Site from DM). | (b) (4), (b) (6) | 04 Nov 2020 20:12:39 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                               | (b) (4), (b) (6) | 04 Nov 2020 20:12:33 |
| User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).                | (b) (4), (b) (6) | 28 Sep 2020 10:54:33 |
| User entered '165' cm                                                                                                                                                                                     | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:59

Weight

| Audit                                                                       | User             | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 04 Nov 2020 20:12:33 |
| User entered '105' kg                                                       | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:59

Height

| Audit                                                                                                                                                                                                     | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).                | (b) (4), (b) (6) | 10 Nov 2020 21:22:10 |
| Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected.' (Site from DM). | (b) (4), (b) (6) | 04 Nov 2020 20:12:39 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                               | (b) (4), (b) (6) | 04 Nov 2020 20:12:33 |
| User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).                | (b) (4), (b) (6) | 28 Sep 2020 10:54:33 |
| User entered '165' cm                                                                                                                                                                                     | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:59

Weight

| Audit                                                                       | User             | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 04 Nov 2020 20:12:33 |
| User entered '105' kg                                                       | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:59

[Timepoint](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

[Were vital signs assessed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '19 Aug 2020' | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| User entered '13:53' | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |



US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 13:53' | System | 20 Aug 2020 20:02:41 |

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:59

Temperature (xxx.x)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered '98.9' F | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

[Route of measurement](#)

| Audit                                                                                                               | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System). | System           | 20 Aug 2020 20:03:03 |
| User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System). | System           | 20 Aug 2020 20:02:41 |
| User entered 'Other (Other)'                                                                                        | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:59

[If Other, specify](#)

| Audit                                                       | User             | Time (GMT)           |
|-------------------------------------------------------------|------------------|----------------------|
| User entered 'tympanic' reason for change: Data Entry Error | (b) (4), (b) (6) | 20 Aug 2020 20:03:03 |
| User entered empty.                                         | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

[Pulse \(xxx\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| User entered '84' | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 20 Aug 2020 20:02:41 |

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:59

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| User entered '16' | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 20 Aug 2020 20:02:41 |



US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| User entered '126' | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Aug 2020 20:02:41 |

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:59

Diastolic Blood Pressure (xxx)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| User entered '76' | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Aug 2020 20:02:41 |

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:59

Height

| Audit                                                                                                                                                                                                     | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).                | (b) (4), (b) (6) | 10 Nov 2020 21:22:10 |
| Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected.' (Site from DM). | (b) (4), (b) (6) | 04 Nov 2020 20:12:39 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                               | (b) (4), (b) (6) | 04 Nov 2020 20:12:33 |
| User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).                | (b) (4), (b) (6) | 28 Sep 2020 10:54:33 |
| User entered '165' cm                                                                                                                                                                                     | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:59

Weight

| Audit                                                                       | User             | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 04 Nov 2020 20:12:33 |
| User entered '105' kg                                                       | (b) (4), (b) (6) | 20 Aug 2020 20:02:41 |

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:59

[Timepoint](#)

| Audit                                              | User             | Time (GMT)           |
|----------------------------------------------------|------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 20 Aug 2020 20:04:06 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

[Were vital signs assessed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 20:04:06 |



US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '19 Aug 2020' | (b) (4), (b) (6) | 20 Aug 2020 20:04:06 |

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                            | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.                                              | System           | 21 Aug 2020 05:43:24 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with ' c ' (Site from System). | (b) (4), (b) (6) | 20 Aug 2020 20:04:21 |
| User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).         | System           | 20 Aug 2020 20:04:06 |
| User entered '15:10'                                                                                                                                             | (b) (4), (b) (6) | 20 Aug 2020 20:04:06 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 15:10' | System | 20 Aug 2020 20:04:06 |

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:59

Temperature (xxx.x)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered '99' F | (b) (4), (b) (6) | 20 Aug 2020 20:04:06 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

[Route of measurement](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| User entered 'Other (Other)' | (b) (4), (b) (6) | 20 Aug 2020 20:04:06 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

[If Other, specify](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| User entered 'tympanic' | (b) (4), (b) (6) | 20 Aug 2020 20:04:06 |

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:59

[Pulse \(xxx\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| User entered '88' | (b) (4), (b) (6) | 20 Aug 2020 20:04:06 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 20 Aug 2020 20:04:06 |



US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:59

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| User entered '16' | (b) (4), (b) (6) | 20 Aug 2020 20:04:06 |
|                   |                  |                      |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 20 Aug 2020 20:04:06 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| User entered '140' | (b) (4), (b) (6) | 20 Aug 2020 20:04:06 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Aug 2020 20:04:06 |

US3462255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:59

Diastolic Blood Pressure (xxx)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| User entered '84' | (b) (4), (b) (6) | 20 Aug 2020 20:04:06 |

US3462255

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:31:59**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Aug 2020 20:04:06 |

US3462255

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:31:59**

[Was the physical examination performed?](#)

| Audit                                                     | User             | Time (GMT)           |
|-----------------------------------------------------------|------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 04:37:10 |
| User entered 'Yes (Y)'                                    | (b) (4), (b) (6) | 20 Aug 2020 20:04:37 |

US3462255

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                                  | User             | Time (GMT)           |
|--------------------------------------------------------|------------------|----------------------|
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Nov 2020 04:37:10 |
| User entered '19 Aug 2020'                             | (b) (4), (b) (6) | 20 Aug 2020 20:04:37 |



US3462255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:59

[Was study treatment given?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:54:26 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:59

[If No, reason not given](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 19 Aug 2020 21:54:26 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 19 Aug 2020 21:54:26 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:31:59**

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:59

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered '19 Aug 2020' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:54:26 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:59

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                | User                  | Time (GMT)           |
|----------------------|-----------------------|----------------------|
| User entered '14:38' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:54:26 |
|                      |                       |                      |
|                      |                       |                      |

US3462255

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:31:59**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 14:38' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:59

[Which arm was used to give treatment?](#)

| Audit                              | User                  | Time (GMT)           |
|------------------------------------|-----------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Danuel Hamlin (b) (4) | 19 Aug 2020 21:54:26 |
|                                    |                       |                      |
|                                    |                       |                      |



US3462255

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:31:59**

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:31:59**

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:31:59**

[Was the sample collected?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 20:09:12 |

US3462255

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:59

Collection date (*dd MMM yyyy*)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '19 Aug 2020' | (b) (4), (b) (6) | 20 Aug 2020 20:09:12 |
|                            |                  |                      |

US3462255

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:31:59**

[Collection time \(00:00-23:59\)](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| User entered '14:33' | (b) (4), (b) (6) | 20 Aug 2020 20:09:12 |

US3462255

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 14:33' | System | 20 Aug 2020 20:09:12 |

US3462255

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '19 Aug 2020' | (b) (4), (b) (6) | 20 Aug 2020 20:09:30 |

US3462255

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Lab Test](#)

| Audit                                                        | User             | Time (GMT)           |
|--------------------------------------------------------------|------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 20 Aug 2020 20:09:30 |



US3462255

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Was the sample collected?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 20:09:30 |

US3462255

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Collection time \(00:00 - 23:59\)](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| User entered '14:30' | (b) (4), (b) (6) | 20 Aug 2020 20:09:30 |
|                      |                  |                      |

US3462255

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 14:30' | System | 20 Aug 2020 20:09:30 |

US3462255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:59

[Lab Test](#)

| Audit                                                        | User             | Time (GMT)           |
|--------------------------------------------------------------|------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 20 Aug 2020 20:09:30 |

US3462255

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Was the sample collected?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 20:09:30 |

US3462255

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Collection time \(00:00 - 23:59\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 20:09:30 |
|                     |                  |                      |

US3462255

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 20:09:30 |

US3462255

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:31:59

[Is the participant continuing to the next visit?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 20:09:37 |



US3462255

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 20:09:37 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:59', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1d4c71ed-0f87-49a8-847a-930583fd3954' | System | 19 Aug 2020 22:12:26 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 19 Aug 2020 22:12:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:12:12', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1d4c71ed-0f87-49a8-847a-930583fd3954' | System | 19 Aug 2020 22:12:26 |
| User entered '99.0'                                                                                                                                                                                                                                            | System | 19 Aug 2020 22:12:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:12:18', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1d4c71ed-0f87-49a8-847a-930583fd3954' | System | 19 Aug 2020 22:12:26 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Aug 2020 22:12:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:12:21', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1d4c71ed-0f87-49a8-847a-930583fd3954' | System | 19 Aug 2020 22:12:26 |
| User entered '19 Aug 2020 15:12'                                                                                                                                                                                                                               | System | 19 Aug 2020 22:12:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 14:58' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 17:28' | System | 19 Aug 2020 21:54:26 |



US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 1, after vaccination (at home)' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:49', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c69df7d-e2d3-4367-9cab-a8bc3d7201e8' | System | 20 Aug 2020 01:41:26 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 20 Aug 2020 01:41:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:41:07', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c69df7d-e2d3-4367-9cab-a8bc3d7201e8' | System | 20 Aug 2020 01:41:26 |
| User entered '97.2'                                                                                                                                                                                                                                            | System | 20 Aug 2020 01:41:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:41:15', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c69df7d-e2d3-4367-9cab-a8bc3d7201e8' | System | 20 Aug 2020 01:41:26 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Aug 2020 01:41:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:41:19', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c69df7d-e2d3-4367-9cab-a8bc3d7201e8' | System | 20 Aug 2020 01:41:26 |
| User entered '19 Aug 2020 18:41'                                                                                                                                                                                                                               | System | 20 Aug 2020 01:41:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 18:23' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 2' | System | 19 Aug 2020 21:54:26 |



US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:31:59

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:41', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '76549c8a-e62c-4eef-8c4b-ba052c1e41a3' | System | 21 Aug 2020 00:15:07 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 21 Aug 2020 00:15:07 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:31:59

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:50', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '76549c8a-e62c-4eef-8c4b-ba052c1e41a3' | System | 21 Aug 2020 00:15:07 |
| User entered '98.5'                                                                                                                                                                                                                                            | System | 21 Aug 2020 00:15:07 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:56', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '76549c8a-e62c-4eef-8c4b-ba052c1e41a3' | System | 21 Aug 2020 00:15:07 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Aug 2020 00:15:07 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:59', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '76549c8a-e62c-4eef-8c4b-ba052c1e41a3' | System | 21 Aug 2020 00:15:07 |
| User entered '20 Aug 2020 17:14'                                                                                                                                                                                                                               | System | 21 Aug 2020 00:15:07 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 3' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:31:59

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:03', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'd6da38bf-e821-4447-9da1-3d28afcd2d7b' | System | 22 Aug 2020 03:21:39 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 22 Aug 2020 03:21:39 |



US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:31:59

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:17', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'd6da38bf-e821-4447-9da1-3d28afcd2d7b' | System | 22 Aug 2020 03:21:39 |
| User entered '97.3'                                                                                                                                                                                                                                            | System | 22 Aug 2020 03:21:39 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:25', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'd6da38bf-e821-4447-9da1-3d28afcd2d7b' | System | 22 Aug 2020 03:21:39 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Aug 2020 03:21:39 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:29', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'd6da38bf-e821-4447-9da1-3d28afcd2d7b' | System | 22 Aug 2020 03:21:39 |
| User entered '21 Aug 2020 20:21'                                                                                                                                                                                                                               | System | 22 Aug 2020 03:21:39 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 4' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:31:59

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T16:59:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2240d201-b1e8-4088-bdb8-12b1a370cafa' | System | 23 Aug 2020 00:00:13 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 23 Aug 2020 00:00:13 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

Please record your **TEMPERATURE in °F**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T16:59:54', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2240d201-b1e8-4088-bdb8-12b1a370cafa' | System | 23 Aug 2020 00:00:13 |
| User entered '98.5'                                                                                                                                                                                                                                            | System | 23 Aug 2020 00:00:13 |



US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:00:03', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2240d201-b1e8-4088-bdb8-12b1a370cafa' | System | 23 Aug 2020 00:00:13 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Aug 2020 00:00:13 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:00:09', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2240d201-b1e8-4088-bdb8-12b1a370cafa' | System | 23 Aug 2020 00:00:13 |
| User entered '22 Aug 2020 17:00'                                                                                                                                                                                                                               | System | 23 Aug 2020 00:00:13 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 5' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:31:59

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:14:20', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '738f30ae-88ff-4d4b-9c04-1a017c60756f' User entered 'Yes (Y)' | System | 24 Aug 2020 00:14:44 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:31:59

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:14:29', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '738f30ae-88ff-4d4b-9c04-1a017c60756f' User entered '98.5' | System | 24 Aug 2020 00:14:44 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:14:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '738f30ae-88ff-4d4b-9c04-1a017c60756f' User entered 'No (N)' | System | 24 Aug 2020 00:14:44 |



US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:14:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '738f30ae-88ff-4d4b-9c04-1a017c60756f' User entered '23 Aug 2020 17:14' | System | 24 Aug 2020 00:14:44 |
|                                                                                                                                                                                                                                                                                                 | System | 24 Aug 2020 00:14:44 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 6' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:31:59

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:06', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '6a471a49-e4ac-4b59-96ad-fbb76476db23' | System | 24 Aug 2020 23:33:40 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 24 Aug 2020 23:33:40 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

Please record your **TEMPERATURE in °F**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:17', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '6a471a49-e4ac-4b59-96ad-fbb76476db23' | System | 24 Aug 2020 23:33:40 |
| User entered '98.5'                                                                                                                                                                                                                                            | System | 24 Aug 2020 23:33:40 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:23', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '6a471a49-e4ac-4b59-96ad-fbb76476db23' | System | 24 Aug 2020 23:33:40 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Aug 2020 23:33:40 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:35', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '6a471a49-e4ac-4b59-96ad-fbb76476db23' User entered '24 Aug 2020 16:33' | System | 24 Aug 2020 23:33:40 |
|                                                                                                                                                                                                                                                                                                 | System | 24 Aug 2020 23:33:40 |



US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 7' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:31:59

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:18:26', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '5d82c9d6-5399-41c5-be28-ddfe235fae0a' | System | 26 Aug 2020 10:18:48 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 26 Aug 2020 10:18:48 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:31:59

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:18:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '5d82c9d6-5399-41c5-be28-ddfe235fae0a' User entered '98.6' | System | 26 Aug 2020 10:18:48 |
|                                                                                                                                                                                                                                                                                    | System | 26 Aug 2020 10:18:48 |

US3462255

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:18:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '5d82c9d6-5399-41c5-be28-ddfe235fae0a' | System | 26 Aug 2020 10:18:48 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 26 Aug 2020 10:18:48 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:18:44', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '5d82c9d6-5399-41c5-be28-ddfe235fae0a' | System | 26 Aug 2020 10:18:48 |
| User entered '26 Aug 2020 03:18'                                                                                                                                                                                                                               | System | 26 Aug 2020 10:18:48 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |



US3462255

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:10:35', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'eadb66cf-9d90-41c2-9dd6-c0bdf694789c' | System | 19 Aug 2020 22:11:04 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 19 Aug 2020 22:11:04 |

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:10:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'eadb66cf-9d90-41c2-9dd6-c0bdf694789c' | System | 19 Aug 2020 22:11:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Aug 2020 22:11:04 |

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:10:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'eadb66cf-9d90-41c2-9dd6-c0bdf694789c' | System | 19 Aug 2020 22:11:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Aug 2020 22:11:04 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:10:54', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'eadb66cf-9d90-41c2-9dd6-c0bdf694789c' | System | 19 Aug 2020 22:11:04 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 19 Aug 2020 22:11:04 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:10:59', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'eadb66cf-9d90-41c2-9dd6-c0bdf694789c' | System | 19 Aug 2020 22:11:04 |
| User entered '19 Aug 2020 15:10'                                                                                                                                                                                                                               | System | 19 Aug 2020 22:11:04 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 14:58' | System | 19 Aug 2020 21:54:26 |



US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 17:28' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 1, after vaccination (at home)' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:39:29', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0a0310cd-f710-4eed-8f84-02afad6a54ca' | System | 20 Aug 2020 01:39:59 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 20 Aug 2020 01:39:59 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:39:34', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0a0310cd-f710-4eed-8f84-02afad6a54ca' | System | 20 Aug 2020 01:39:59 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Aug 2020 01:39:59 |

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:39:41', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0a0310cd-f710-4eed-8f84-02afad6a54ca' | System | 20 Aug 2020 01:39:59 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Aug 2020 01:39:59 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:39:48', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0a0310cd-f710-4eed-8f84-02afad6a54ca' | System | 20 Aug 2020 01:39:59 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 20 Aug 2020 01:39:59 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:39:52', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0a0310cd-f710-4eed-8f84-02afad6a54ca' | System | 20 Aug 2020 01:39:59 |
| User entered '19 Aug 2020 18:39'                                                                                                                                                                                                                               | System | 20 Aug 2020 01:39:59 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 18:23' | System | 19 Aug 2020 21:54:26 |



US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 2' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f9dc4dd1-9ad9-4835-9bb7-87e6775ef838' | System | 21 Aug 2020 00:14:35 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 21 Aug 2020 00:14:35 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:15', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f9dc4dd1-9ad9-4835-9bb7-87e6775ef838' | System | 21 Aug 2020 00:14:35 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Aug 2020 00:14:35 |

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:20', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f9dc4dd1-9ad9-4835-9bb7-87e6775ef838' | System | 21 Aug 2020 00:14:35 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Aug 2020 00:14:35 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:28', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f9dc4dd1-9ad9-4835-9bb7-87e6775ef838' | System | 21 Aug 2020 00:14:35 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 21 Aug 2020 00:14:35 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:14:32', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f9dc4dd1-9ad9-4835-9bb7-87e6775ef838' | System | 21 Aug 2020 00:14:35 |
| User entered '20 Aug 2020 17:14'                                                                                                                                                                                                                               | System | 21 Aug 2020 00:14:35 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |



US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 3' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:35', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'aa48802d-d297-449c-a6a0-3ffda940d07d' | System | 22 Aug 2020 03:21:59 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 03:21:59 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'aa48802d-d297-449c-a6a0-3ffda940d07d' | System | 22 Aug 2020 03:21:59 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Aug 2020 03:21:59 |

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:47', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'aa48802d-d297-449c-a6a0-3ffda940d07d' | System | 22 Aug 2020 03:21:59 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Aug 2020 03:21:59 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:51', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'aa48802d-d297-449c-a6a0-3ffda940d07d' | System | 22 Aug 2020 03:21:59 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 03:21:59 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:21:54', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'aa48802d-d297-449c-a6a0-3ffda940d07d' | System | 22 Aug 2020 03:21:59 |
| User entered '21 Aug 2020 20:21'                                                                                                                                                                                                                               | System | 22 Aug 2020 03:21:59 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |



US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 4' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:00:25', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '83f6b537-de28-4451-88b3-6f42f9e41337' | System | 23 Aug 2020 00:00:56 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 23 Aug 2020 00:00:56 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:00:32', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '83f6b537-de28-4451-88b3-6f42f9e41337' | System | 23 Aug 2020 00:00:56 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Aug 2020 00:00:56 |

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:00:43', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '83f6b537-de28-4451-88b3-6f42f9e41337' | System | 23 Aug 2020 00:00:56 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Aug 2020 00:00:56 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:00:49', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '83f6b537-de28-4451-88b3-6f42f9e41337' | System | 23 Aug 2020 00:00:56 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 23 Aug 2020 00:00:56 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:00:52', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '83f6b537-de28-4451-88b3-6f42f9e41337' | System | 23 Aug 2020 00:00:56 |
| User entered '22 Aug 2020 17:00'                                                                                                                                                                                                                               | System | 23 Aug 2020 00:00:56 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |



US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 5' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:14:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b179442e-61f5-418a-97a7-5e806451c8e2' | System | 24 Aug 2020 00:15:08 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 00:15:08 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:14:51', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b179442e-61f5-418a-97a7-5e806451c8e2' | System | 24 Aug 2020 00:15:08 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Aug 2020 00:15:08 |

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:14:56', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b179442e-61f5-418a-97a7-5e806451c8e2' | System | 24 Aug 2020 00:15:08 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Aug 2020 00:15:08 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:14:59', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b179442e-61f5-418a-97a7-5e806451c8e2' | System | 24 Aug 2020 00:15:08 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 00:15:08 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:03', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b179442e-61f5-418a-97a7-5e806451c8e2' | System | 24 Aug 2020 00:15:08 |
| User entered '23 Aug 2020 17:15'                                                                                                                                                                                                                               | System | 24 Aug 2020 00:15:08 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |



US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 6' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:41', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3c71e77e-d3b4-4996-bc95-9aec9eda10e9' | System | 24 Aug 2020 23:34:02 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 23:34:02 |

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:31:59

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:45', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3c71e77e-d3b4-4996-bc95-9aec9eda10e9' | System | 24 Aug 2020 23:34:02 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Aug 2020 23:34:02 |

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:50', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3c71e77e-d3b4-4996-bc95-9aec9eda10e9' | System | 24 Aug 2020 23:34:02 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Aug 2020 23:34:02 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:55', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3c71e77e-d3b4-4996-bc95-9aec9eda10e9' | System | 24 Aug 2020 23:34:02 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 23:34:02 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:33:58', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3c71e77e-d3b4-4996-bc95-9aec9eda10e9' User entered '24 Aug 2020 16:33' | System | 24 Aug 2020 23:34:02 |
|                                                                                                                                                                                                                                                                                                 | System | 24 Aug 2020 23:34:02 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |



US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 7' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:18:50', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2cba7ea1-bf9f-4bce-a502-2e359e18807a' User entered 'None (1)' | System | 26 Aug 2020 10:19:11 |
|                                                                                                                                                                                                                                                                                        | System | 26 Aug 2020 10:19:11 |

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:31:59

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:18:54', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2cba7ea1-bf9f-4bce-a502-2e359e18807a' | System | 26 Aug 2020 10:19:11 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 26 Aug 2020 10:19:11 |

US3462255

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:18:58', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2cba7ea1-bf9f-4bce-a502-2e359e18807a' User entered 'No (N)' | System | 26 Aug 2020 10:19:11 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:02', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2cba7ea1-bf9f-4bce-a502-2e359e18807a' User entered 'None (1)' | System | 26 Aug 2020 10:19:11 |
|                                                                                                                                                                                                                                                                                        | System | 26 Aug 2020 10:19:11 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:06', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2cba7ea1-bf9f-4bce-a502-2e359e18807a' User entered '26 Aug 2020 03:19' | System | 26 Aug 2020 10:19:11 |
|                                                                                                                                                                                                                                                                                                 | System | 26 Aug 2020 10:19:11 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |



US3462255

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:11', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ce49a0f-8638-4192-936d-3c9e2aeffd1b' | System | 19 Aug 2020 22:11:46 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Aug 2020 22:11:46 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:17', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ce49a0f-8638-4192-936d-3c9e2aeffd1b' | System | 19 Aug 2020 22:11:46 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Aug 2020 22:11:46 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:21', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ce49a0f-8638-4192-936d-3c9e2aeffd1b' | System | 19 Aug 2020 22:11:46 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Aug 2020 22:11:46 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:24', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ce49a0f-8638-4192-936d-3c9e2aeffd1b' | System | 19 Aug 2020 22:11:46 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Aug 2020 22:11:46 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:27', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ce49a0f-8638-4192-936d-3c9e2aeffd1b' | System | 19 Aug 2020 22:11:46 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Aug 2020 22:11:46 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:31', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ce49a0f-8638-4192-936d-3c9e2aeffd1b' | System | 19 Aug 2020 22:11:46 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Aug 2020 22:11:46 |



US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:41', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ce49a0f-8638-4192-936d-3c9e2aeffd1b' | System | 19 Aug 2020 22:11:46 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Aug 2020 22:11:46 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T15:11:44', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ce49a0f-8638-4192-936d-3c9e2aeffd1b' | System | 19 Aug 2020 22:11:46 |
| User entered '19 Aug 2020 15:11'                                                                                                                                                                                                                               | System | 19 Aug 2020 22:11:46 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 14:58' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 17:28' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 1, after vaccination (at home)' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:05', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a52d89f-40d8-41bc-9f7b-1c52f5bdc29b' | System | 20 Aug 2020 01:40:50 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Aug 2020 01:40:50 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:09', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a52d89f-40d8-41bc-9f7b-1c52f5bdc29b' | System | 20 Aug 2020 01:40:50 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Aug 2020 01:40:50 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:15', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a52d89f-40d8-41bc-9f7b-1c52f5bdc29b' | System | 20 Aug 2020 01:40:50 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Aug 2020 01:40:50 |



US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:20', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a52d89f-40d8-41bc-9f7b-1c52f5bdc29b' | System | 20 Aug 2020 01:40:50 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Aug 2020 01:40:50 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:29', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a52d89f-40d8-41bc-9f7b-1c52f5bdc29b' | System | 20 Aug 2020 01:40:50 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Aug 2020 01:40:50 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:32', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a52d89f-40d8-41bc-9f7b-1c52f5bdc29b' | System | 20 Aug 2020 01:40:50 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Aug 2020 01:40:50 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:37', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a52d89f-40d8-41bc-9f7b-1c52f5bdc29b' | System | 20 Aug 2020 01:40:50 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Aug 2020 01:40:50 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-19T18:40:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '4a52d89f-40d8-41bc-9f7b-1c52f5bdc29b' | System | 20 Aug 2020 01:40:50 |
| User entered '19 Aug 2020 18:40'                                                                                                                                                                                                                               | System | 20 Aug 2020 01:40:50 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 18:23' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 2' | System | 19 Aug 2020 21:54:26 |



US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:15:05', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '412a082d-cea2-41c4-b45f-12d4c80557ee' User entered 'None (0)' | System | 21 Aug 2020 00:15:48 |
|                                                                                                                                                                                                                                                                                        | System | 21 Aug 2020 00:15:48 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:15:15', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '412a082d-cea2-41c4-b45f-12d4c80557ee' User entered 'None (0)' | System | 21 Aug 2020 00:15:48 |
|                                                                                                                                                                                                                                                                                        | System | 21 Aug 2020 00:15:48 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:15:21', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '412a082d-cea2-41c4-b45f-12d4c80557ee' User entered 'None (0)' | System | 21 Aug 2020 00:15:48 |
|                                                                                                                                                                                                                                                                                        | System | 21 Aug 2020 00:15:48 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:15:27', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '412a082d-cea2-41c4-b45f-12d4c80557ee' User entered 'None (0)' | System | 21 Aug 2020 00:15:48 |
|                                                                                                                                                                                                                                                                                        | System | 21 Aug 2020 00:15:48 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:15:31', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '412a082d-cea2-41c4-b45f-12d4c80557ee' | System | 21 Aug 2020 00:15:48 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Aug 2020 00:15:48 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:15:35', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '412a082d-cea2-41c4-b45f-12d4c80557ee' User entered 'None (0)' | System | 21 Aug 2020 00:15:48 |
|                                                                                                                                                                                                                                                                                        | System | 21 Aug 2020 00:15:48 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:15:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '412a082d-cea2-41c4-b45f-12d4c80557ee' | System | 21 Aug 2020 00:15:48 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Aug 2020 00:15:48 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-20T17:15:43', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '412a082d-cea2-41c4-b45f-12d4c80557ee' User entered '20 Aug 2020 17:15' | System | 21 Aug 2020 00:15:48 |
|                                                                                                                                                                                                                                                                                                 | System | 21 Aug 2020 00:15:48 |



US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 3' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:22:01', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '78837591-ebe5-4119-b348-190558ea9410' | System | 22 Aug 2020 03:22:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 03:22:32 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:22:05', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '78837591-ebe5-4119-b348-190558ea9410' | System | 22 Aug 2020 03:22:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 03:22:32 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:22:09', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '78837591-ebe5-4119-b348-190558ea9410' | System | 22 Aug 2020 03:22:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 03:22:32 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:22:12', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '78837591-ebe5-4119-b348-190558ea9410' | System | 22 Aug 2020 03:22:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 03:22:32 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:22:17', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '78837591-ebe5-4119-b348-190558ea9410' | System | 22 Aug 2020 03:22:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 03:22:32 |



US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:22:21', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '78837591-ebe5-4119-b348-190558ea9410' | System | 22 Aug 2020 03:22:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Aug 2020 03:22:32 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:22:24', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '78837591-ebe5-4119-b348-190558ea9410' | System | 22 Aug 2020 03:22:32 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Aug 2020 03:22:32 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-21T20:22:28', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '78837591-ebe5-4119-b348-190558ea9410' | System | 22 Aug 2020 03:22:32 |
| User entered '21 Aug 2020 20:22'                                                                                                                                                                                                                               | System | 22 Aug 2020 03:22:32 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 4' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:01:05', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fdd8ccd6-fed4-4936-ad47-cc7eda706f2e' User entered 'None (0)' | System | 23 Aug 2020 00:02:12 |
|                                                                                                                                                                                                                                                                                        | System | 23 Aug 2020 00:02:12 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:01:15', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fdd8ccd6-fed4-4936-ad47-cc7eda706f2e' | System | 23 Aug 2020 00:02:12 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 23 Aug 2020 00:02:12 |



US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:01:28', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fdd8ccd6-fed4-4936-ad47-cc7eda706f2e' | System | 23 Aug 2020 00:02:12 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 23 Aug 2020 00:02:12 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:01:38', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fdd8ccd6-fed4-4936-ad47-cc7eda706f2e' | System | 23 Aug 2020 00:02:12 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 23 Aug 2020 00:02:12 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:01:42', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fdd8ccd6-fed4-4936-ad47-cc7eda706f2e' User entered 'None (0)' | System | 23 Aug 2020 00:02:12 |
|                                                                                                                                                                                                                                                                                        | System | 23 Aug 2020 00:02:12 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:01:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fdd8ccd6-fed4-4936-ad47-cc7eda706f2e' User entered 'None (0)' | System | 23 Aug 2020 00:02:12 |
|                                                                                                                                                                                                                                                                                        | System | 23 Aug 2020 00:02:12 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:01:55', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fdd8ccd6-fed4-4936-ad47-cc7eda706f2e' | System | 23 Aug 2020 00:02:12 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Aug 2020 00:02:12 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-22T17:01:58', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fdd8ccd6-fed4-4936-ad47-cc7eda706f2e' User entered '22 Aug 2020 17:01' | System | 23 Aug 2020 00:02:12 |
|                                                                                                                                                                                                                                                                                                 | System | 23 Aug 2020 00:02:12 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |



US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 5' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:09', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ff8b2271-7f7d-45b0-bb13-867bd279a16a' | System | 24 Aug 2020 00:15:37 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 00:15:37 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:13', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ff8b2271-7f7d-45b0-bb13-867bd279a16a' | System | 24 Aug 2020 00:15:37 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 00:15:37 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:16', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ff8b2271-7f7d-45b0-bb13-867bd279a16a' | System | 24 Aug 2020 00:15:37 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 00:15:37 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:19', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ff8b2271-7f7d-45b0-bb13-867bd279a16a' | System | 24 Aug 2020 00:15:37 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 00:15:37 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:22', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ff8b2271-7f7d-45b0-bb13-867bd279a16a' | System | 24 Aug 2020 00:15:37 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 00:15:37 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:25', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ff8b2271-7f7d-45b0-bb13-867bd279a16a' | System | 24 Aug 2020 00:15:37 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 00:15:37 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:29', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ff8b2271-7f7d-45b0-bb13-867bd279a16a' | System | 24 Aug 2020 00:15:37 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Aug 2020 00:15:37 |



US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-23T17:15:32', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ff8b2271-7f7d-45b0-bb13-867bd279a16a' | System | 24 Aug 2020 00:15:37 |
| User entered '23 Aug 2020 17:15'                                                                                                                                                                                                                               | System | 24 Aug 2020 00:15:37 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 6' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:34:03', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b6eaebf7-064d-4e63-aacf-24b72d5fd138' | System | 24 Aug 2020 23:34:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 23:34:44 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:34:06', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b6eaebf7-064d-4e63-aacf-24b72d5fd138' | System | 24 Aug 2020 23:34:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 23:34:44 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:34:11', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b6eaebf7-064d-4e63-aacf-24b72d5fd138' | System | 24 Aug 2020 23:34:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 23:34:44 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:34:20', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b6eaebf7-064d-4e63-aacf-24b72d5fd138' | System | 24 Aug 2020 23:34:44 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 24 Aug 2020 23:34:44 |



US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:34:23', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b6eaebf7-064d-4e63-aacf-24b72d5fd138' | System | 24 Aug 2020 23:34:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 23:34:44 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:34:27', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b6eaebf7-064d-4e63-aacf-24b72d5fd138' | System | 24 Aug 2020 23:34:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 24 Aug 2020 23:34:44 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:34:33', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b6eaebf7-064d-4e63-aacf-24b72d5fd138' | System | 24 Aug 2020 23:34:44 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Aug 2020 23:34:44 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-24T16:34:41', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b6eaebf7-064d-4e63-aacf-24b72d5fd138' | System | 24 Aug 2020 23:34:44 |
| User entered '24 Aug 2020 16:34'                                                                                                                                                                                                                               | System | 24 Aug 2020 23:34:44 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 7' | System | 19 Aug 2020 21:54:26 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:12', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c71ff20-0e92-4591-9dad-cbfde6b01d4c' | System | 26 Aug 2020 10:19:41 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 10:19:41 |



US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:15', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c71ff20-0e92-4591-9dad-cbfde6b01d4c' | System | 26 Aug 2020 10:19:41 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 10:19:41 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:18', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c71ff20-0e92-4591-9dad-cbfde6b01d4c' | System | 26 Aug 2020 10:19:41 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 10:19:41 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:22', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c71ff20-0e92-4591-9dad-cbfde6b01d4c' | System | 26 Aug 2020 10:19:41 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 10:19:41 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:25', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c71ff20-0e92-4591-9dad-cbfde6b01d4c' | System | 26 Aug 2020 10:19:41 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 10:19:41 |

US3462255

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:28', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c71ff20-0e92-4591-9dad-cbfde6b01d4c' User entered 'None (0)' | System | 26 Aug 2020 10:19:41 |
|                                                                                                                                                                                                                                                                                        | System | 26 Aug 2020 10:19:41 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:33', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c71ff20-0e92-4591-9dad-cbfde6b01d4c' | System | 26 Aug 2020 10:19:41 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 26 Aug 2020 10:19:41 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-08-26T03:19:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9c71ff20-0e92-4591-9dad-cbfde6b01d4c' User entered '26 Aug 2020 03:19' | System | 26 Aug 2020 10:19:41 |
|                                                                                                                                                                                                                                                                                                 | System | 26 Aug 2020 10:19:41 |

US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 12:00' | System | 19 Aug 2020 21:54:26 |



US3462255

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 19 Aug 2020 21:54:26 |

US3462255

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Was Contact Attempted?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:04:12 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                                              | Time (GMT)           |
|----------------------------|---------------------------------------------------|----------------------|
| User entered '26 Aug 2020' | Danuel Hamlin (b) (4)<br>[REDACTED]<br>[REDACTED] | 16 Sep 2020 21:04:12 |

US3462255

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:04:12 |
|                                            |                       |                      |
|                                            |                       |                      |

US3462255

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 16 Sep 2020 21:04:12 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:04:19 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 16 Sep 2020 21:04:19 |

US3462255

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Was Contact Attempted?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:04:35 |
|                        |                       |                      |
|                        |                       |                      |



US3462255

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered '02 Sep 2020' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:04:35 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:04:35 |
|                                            |                       |                      |
|                                            |                       |                      |

US3462255

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 16 Sep 2020 21:04:35 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:04:45 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 16 Sep 2020 21:04:45 |

US3462255

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Was Contact Attempted?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:05:20 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered '09 Sep 2020' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:05:20 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:05:20 |
|                                            |                       |                      |
|                                            |                       |                      |



US3462255

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 16 Sep 2020 21:05:20 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:05:27 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 16 Sep 2020 21:05:27 |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:59

[Was this visit performed?](#)

| Audit                                                                                                                                                                                                                                                                                                                                                          | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.<br>' (Site from DM).           | (b) (4), (b) (6)      | 25 Nov 2020 02:45:46 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.<br>' answered with 'Added' (Site from DM). | Danuel Hamlin (b) (4) | 06 Nov 2020 01:10:31 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.<br>' (Site from DM).           | (b) (4), (b) (6)      | 02 Nov 2020 08:48:10 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                                                                                                         | Danuel Hamlin (b) (4) | 16 Sep 2020 21:05:41 |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered '16 Sep 2020' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:05:41 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| User entered 'Clinic (Clinic)' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:05:41 |
|                                |                       |                      |
|                                |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:31:59**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 16 Sep 2020 21:05:41 |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:59

[Timepoint](#)

| Audit                                            | User                  | Time (GMT)           |
|--------------------------------------------------|-----------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                                                  |                       |                      |
|                                                  |                       |                      |



US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

[Were vital signs assessed?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered '16 Sep 2020' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                  | Time (GMT)           |
|----------------------|-----------------------|----------------------|
| User entered '13:14' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                      |                       |                      |
|                      |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 13:14' | System | 24 Sep 2020 20:27:47 |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:59

Temperature (xxx.x)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| User entered '97.3' F | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                       |                       |                      |
|                       |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

[Route of measurement](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| User entered 'Other (Other)' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                              |                       |                      |
|                              |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

[If Other, specify](#)

| Audit                   | User                  | Time (GMT)           |
|-------------------------|-----------------------|----------------------|
| User entered 'TYMPANIC' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                         |                       |                      |
|                         |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

[Pulse \(xxx\)](#)

| Audit             | User                  | Time (GMT)           |
|-------------------|-----------------------|----------------------|
| User entered '90' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                   |                       |                      |
|                   |                       |                      |



US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 24 Sep 2020 20:27:47 |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:59

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

| Audit             | User                  | Time (GMT)           |
|-------------------|-----------------------|----------------------|
| User entered '16' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                   |                       |                      |
|                   |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 24 Sep 2020 20:27:47 |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit              | User                  | Time (GMT)           |
|--------------------|-----------------------|----------------------|
| User entered '130' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                    |                       |                      |
|                    |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Sep 2020 20:27:47 |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit             | User                  | Time (GMT)           |
|-------------------|-----------------------|----------------------|
| User entered '74' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                   |                       |                      |
|                   |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Sep 2020 20:27:47 |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:59

[Timepoint](#)

| Audit                                              | User                  | Time (GMT)           |
|----------------------------------------------------|-----------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                                                    |                       |                      |
|                                                    |                       |                      |



US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:59

[Were vital signs assessed?](#)

| Audit                                                                                  | User                                | Time (GMT)           |
|----------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                              | 24 Sep 2020 20:27:53 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                              | 24 Sep 2020 20:27:53 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | Danuel Hamlin (b) (4)<br>[REDACTED] | 24 Sep 2020 20:27:53 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                              | 24 Sep 2020 20:27:47 |
| User entered empty.                                                                    | Danuel Hamlin (b) (4)<br>[REDACTED] | 24 Sep 2020 20:27:47 |

US3462255

**Folder:** Visit 2 Day 29 (1)

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

**Generated On:** 26 Nov 2020 09:31:59

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered '16 Sep 2020' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                  | Time (GMT)           |
|----------------------|-----------------------|----------------------|
| User entered '14:16' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                      |                       |                      |
|                      |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 14:16' | System | 24 Sep 2020 20:27:47 |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:59

Temperature (xxx.x)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| User entered '98.9' F | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                       |                       |                      |
|                       |                       |                      |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:59

[Route of measurement](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| User entered 'Other (Other)' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                              |                       |                      |
|                              |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

[If Other, specify](#)

| Audit                   | User                  | Time (GMT)           |
|-------------------------|-----------------------|----------------------|
| User entered 'TYMPANIC' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                         |                       |                      |
|                         |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

[Pulse \(xxx\)](#)

| Audit             | User                  | Time (GMT)           |
|-------------------|-----------------------|----------------------|
| User entered '90' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                   |                       |                      |
|                   |                       |                      |



US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 24 Sep 2020 20:27:47 |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit             | User                  | Time (GMT)           |
|-------------------|-----------------------|----------------------|
| User entered '18' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                   |                       |                      |
|                   |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 24 Sep 2020 20:27:47 |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit              | User                  | Time (GMT)           |
|--------------------|-----------------------|----------------------|
| User entered '124' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                    |                       |                      |
|                    |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Sep 2020 20:27:47 |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit             | User                  | Time (GMT)           |
|-------------------|-----------------------|----------------------|
| User entered '78' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:27:47 |
|                   |                       |                      |
|                   |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:31:59**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Sep 2020 20:27:47 |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:31:59**

[Was the physical examination performed?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:28:00 |
|                       |                       |                      |
|                       |                       |                      |



US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 24 Sep 2020 20:28:00 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:59

[Was study treatment given?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:06:05 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:59

[If No, reason not given](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 16 Sep 2020 21:06:05 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 16 Sep 2020 21:06:05 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:31:59**

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:59

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered '16 Sep 2020' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:06:05 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:31:59

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                | User                  | Time (GMT)           |
|----------------------|-----------------------|----------------------|
| User entered '13:44' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:06:05 |
|                      |                       |                      |
|                      |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:31:59**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 13:44' | System | 16 Sep 2020 21:06:05 |



US3462255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:59

[Which arm was used to give treatment?](#)

| Audit                              | User                  | Time (GMT)           |
|------------------------------------|-----------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Danuel Hamlin (b) (4) | 16 Sep 2020 21:06:05 |
|                                    |                       |                      |
|                                    |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:31:59**

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:31:59**

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:31:59**

[Was the sample collected?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:28:33 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:31:59**

Collection date (dd MMM yyyy)

| Audit                                                                                                                                   | User                                | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).                    | System                              | 24 Sep 2020 20:28:46 |
| Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System). |                                     | 24 Sep 2020 20:28:46 |
| User entered '16 Sep 2020' reason for change: Data Entry Error                                                                          | Danuel Hamlin (b) (4)<br>[REDACTED] | 24 Sep 2020 20:28:46 |
| User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).                    | System                              | 24 Sep 2020 20:28:33 |
| User entered '14 Sep 2020'                                                                                                              | Danuel Hamlin (b) (4)<br>[REDACTED] | 24 Sep 2020 20:28:33 |

US3462255

**Folder:** Visit 2 Day 29 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 09:31:59

[Collection time \(00:00-23:59\)](#)

| Audit                | User                  | Time (GMT)           |
|----------------------|-----------------------|----------------------|
| User entered '14:16' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:28:33 |
|                      |                       |                      |
|                      |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 14:16' | System | 24 Sep 2020 20:28:46 |
| User entered '14 Sep 2020 14:16' | System | 24 Sep 2020 20:28:33 |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered '16 Sep 2020' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:29:14 |
|                            |                       |                      |
|                            |                       |                      |



US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Lab Test](#)

| Audit                                                        | User                  | Time (GMT)           |
|--------------------------------------------------------------|-----------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:29:14 |
|                                                              |                       |                      |
|                                                              |                       |                      |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:59

[Was the sample collected?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:29:14 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Collection time \(00:00 - 23:59\)](#)

| Audit                | User                  | Time (GMT)           |
|----------------------|-----------------------|----------------------|
| User entered '13:31' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:29:14 |
|                      |                       |                      |
|                      |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 13:31' | System | 24 Sep 2020 20:29:14 |

US3462255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:59

[Lab Test](#)

| Audit                                                        | User                  | Time (GMT)           |
|--------------------------------------------------------------|-----------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:29:14 |
|                                                              |                       |                      |
|                                                              |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Was the sample collected?](#)

| Audit                                                     | User                  | Time (GMT)           |
|-----------------------------------------------------------|-----------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6)      | 11 Oct 2020 23:52:00 |
| User entered 'Yes (Y)'                                    | Danuel Hamlin (b) (4) | 24 Sep 2020 20:29:14 |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Collection time \(00:00 - 23:59\)](#)

| Audit                                                  | User                  | Time (GMT)           |
|--------------------------------------------------------|-----------------------|----------------------|
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 11 Oct 2020 23:52:00 |
|                                                        |                       |                      |
| User entered '13:31'                                   | Danuel Hamlin (b) (4) | 24 Sep 2020 20:29:14 |
|                                                        |                       |                      |
|                                                        |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered empty.              | System | 11 Oct 2020 23:52:00 |
| User entered '16 Sep 2020 13:31' | System | 24 Sep 2020 20:29:14 |



US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 24 Sep 2020 20:29:19 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 24 Sep 2020 20:29:19 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:20:24', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f2424ca4-6165-4a82-b375-9b817ab50449' | System | 16 Sep 2020 21:21:00 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 16 Sep 2020 21:21:00 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:20:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f2424ca4-6165-4a82-b375-9b817ab50449' | System | 16 Sep 2020 21:21:00 |
| User entered '98.9'                                                                                                                                                                                                                                            | System | 16 Sep 2020 21:21:00 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:20:45', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f2424ca4-6165-4a82-b375-9b817ab50449' | System | 16 Sep 2020 21:21:00 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 16 Sep 2020 21:21:00 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:20:55', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f2424ca4-6165-4a82-b375-9b817ab50449' | System | 16 Sep 2020 21:21:00 |
| User entered '16 Sep 2020 14:20'                                                                                                                                                                                                                               | System | 16 Sep 2020 21:21:00 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 14:04' | System | 16 Sep 2020 21:06:05 |



US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 16:34' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 1, after vaccination (at home)' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:05:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '6a214e53-3f04-40c2-8d32-4e4774d92141' | System | 17 Sep 2020 01:06:16 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 17 Sep 2020 01:06:16 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:05:45', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '6a214e53-3f04-40c2-8d32-4e4774d92141' | System | 17 Sep 2020 01:06:16 |
| User entered '98.6'                                                                                                                                                                                                                                            | System | 17 Sep 2020 01:06:16 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:06:09', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '6a214e53-3f04-40c2-8d32-4e4774d92141' | System | 17 Sep 2020 01:06:16 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 17 Sep 2020 01:06:16 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:06:13', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '6a214e53-3f04-40c2-8d32-4e4774d92141' | System | 17 Sep 2020 01:06:16 |
| User entered '16 Sep 2020 18:06'                                                                                                                                                                                                                               | System | 17 Sep 2020 01:06:16 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 17:29' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |



US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 2' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:31:59

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:33:33', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0c8b9df6-b87b-40fe-bc54-496709d35104' | System | 18 Sep 2020 01:33:53 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 18 Sep 2020 01:33:53 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:31:59

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:33:42', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0c8b9df6-b87b-40fe-bc54-496709d35104' User entered '98.6' | System | 18 Sep 2020 01:33:53 |
|                                                                                                                                                                                                                                                                                    | System | 18 Sep 2020 01:33:53 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:33:47', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0c8b9df6-b87b-40fe-bc54-496709d35104' | System | 18 Sep 2020 01:33:53 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 18 Sep 2020 01:33:53 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:33:50', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0c8b9df6-b87b-40fe-bc54-496709d35104' | System | 18 Sep 2020 01:33:53 |
| User entered '17 Sep 2020 18:33'                                                                                                                                                                                                                               | System | 18 Sep 2020 01:33:53 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 3' | System | 16 Sep 2020 21:06:05 |



US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:31:59

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:42:07', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b93dfde9-ed26-4553-92da-807c6d0e0f7d' | System | 19 Sep 2020 01:42:28 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 19 Sep 2020 01:42:28 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

Please record your **TEMPERATURE in °F**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:42:13', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b93dfde9-ed26-4553-92da-807c6d0e0f7d' | System | 19 Sep 2020 01:42:28 |
| User entered '98.2'                                                                                                                                                                                                                                            | System | 19 Sep 2020 01:42:28 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:42:18', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b93dfde9-ed26-4553-92da-807c6d0e0f7d' | System | 19 Sep 2020 01:42:28 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Sep 2020 01:42:28 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:42:21', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b93dfde9-ed26-4553-92da-807c6d0e0f7d' | System | 19 Sep 2020 01:42:28 |
| User entered '18 Sep 2020 18:42'                                                                                                                                                                                                                               | System | 19 Sep 2020 01:42:28 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 4' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:34:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3e45abaf-6e01-4d3e-a029-3803636a862e' | System | 20 Sep 2020 02:35:09 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 20 Sep 2020 02:35:09 |



US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:31:59

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:34:55', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3e45abaf-6e01-4d3e-a029-3803636a862e' User entered '98.5' | System | 20 Sep 2020 02:35:09 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3e45abaf-6e01-4d3e-a029-3803636a862e' User entered 'No (N)' | System | 20 Sep 2020 02:35:09 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:04', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3e45abaf-6e01-4d3e-a029-3803636a862e' | System | 20 Sep 2020 02:35:09 |
| User entered '19 Sep 2020 19:35'                                                                                                                                                                                                                               | System | 20 Sep 2020 02:35:09 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 5' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:31:59

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:26:24', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '5281e2b5-eb90-485d-81f7-cc9455e85ffe' | System | 21 Sep 2020 00:26:43 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 21 Sep 2020 00:26:43 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:31:59

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:26:30', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '5281e2b5-eb90-485d-81f7-cc9455e85ffe' User entered '98.2' | System | 21 Sep 2020 00:26:43 |



US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:26:37', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '5281e2b5-eb90-485d-81f7-cc9455e85ffe' | System | 21 Sep 2020 00:26:43 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Sep 2020 00:26:43 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:26:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '5281e2b5-eb90-485d-81f7-cc9455e85ffe' | System | 21 Sep 2020 00:26:43 |
| User entered '20 Sep 2020 17:26'                                                                                                                                                                                                                               | System | 21 Sep 2020 00:26:43 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 6' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:31:59

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:23:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '97e3acd1-8711-44cd-b6fd-ee7268c60b3f' | System | 22 Sep 2020 01:24:04 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 22 Sep 2020 01:24:04 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:31:59

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:23:52', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '97e3acd1-8711-44cd-b6fd-ee7268c60b3f' User entered '98.6' | System | 22 Sep 2020 01:24:04 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:23:57', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '97e3acd1-8711-44cd-b6fd-ee7268c60b3f' | System | 22 Sep 2020 01:24:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Sep 2020 01:24:04 |



US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '97e3acd1-8711-44cd-b6fd-ee7268c60b3f' User entered '21 Sep 2020 18:24' | System | 22 Sep 2020 01:24:04 |
|                                                                                                                                                                                                                                                                                                 | System | 22 Sep 2020 01:24:04 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 7' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:31:59

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:23:13', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0f157365-3033-4d20-907a-94da663c3204' | System | 23 Sep 2020 00:23:39 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 23 Sep 2020 00:23:39 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:31:59

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:23:22', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0f157365-3033-4d20-907a-94da663c3204' | System | 23 Sep 2020 00:23:39 |
| User entered '96.5'                                                                                                                                                                                                                                            | System | 23 Sep 2020 00:23:39 |

US3462255

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:23:29', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0f157365-3033-4d20-907a-94da663c3204' | System | 23 Sep 2020 00:23:39 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Sep 2020 00:23:39 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:23:34', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '0f157365-3033-4d20-907a-94da663c3204' | System | 23 Sep 2020 00:23:39 |
| User entered '22 Sep 2020 17:23'                                                                                                                                                                                                                               | System | 23 Sep 2020 00:23:39 |



US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:10', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7a0f271c-8b6a-4f77-9ca1-e685c68dc03f' | System | 16 Sep 2020 21:21:35 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 16 Sep 2020 21:21:35 |

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:19', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7a0f271c-8b6a-4f77-9ca1-e685c68dc03f' User entered 'No (N)' | System | 16 Sep 2020 21:21:35 |

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:22', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7a0f271c-8b6a-4f77-9ca1-e685c68dc03f' | System | 16 Sep 2020 21:21:35 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 16 Sep 2020 21:21:35 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:26', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7a0f271c-8b6a-4f77-9ca1-e685c68dc03f' User entered 'None (1)' | System | 16 Sep 2020 21:21:35 |
|                                                                                                                                                                                                                                                                                        | System | 16 Sep 2020 21:21:35 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:30', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7a0f271c-8b6a-4f77-9ca1-e685c68dc03f' User entered '16 Sep 2020 14:21' | System | 16 Sep 2020 21:21:35 |
|                                                                                                                                                                                                                                                                                                 | System | 16 Sep 2020 21:21:35 |



US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 14:04' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 16:34' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 1, after vaccination (at home)' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:06:21', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '780cbe0e-b08d-4aac-b937-3fe43d4f6447' | System | 17 Sep 2020 01:06:52 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 17 Sep 2020 01:06:52 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:06:25', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '780cbe0e-b08d-4aac-b937-3fe43d4f6447' | System | 17 Sep 2020 01:06:52 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 17 Sep 2020 01:06:52 |

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:06:37', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '780cbe0e-b08d-4aac-b937-3fe43d4f6447' | System | 17 Sep 2020 01:06:52 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 17 Sep 2020 01:06:52 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:06:43', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '780cbe0e-b08d-4aac-b937-3fe43d4f6447' | System | 17 Sep 2020 01:06:52 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 17 Sep 2020 01:06:52 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:06:47', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '780cbe0e-b08d-4aac-b937-3fe43d4f6447' | System | 17 Sep 2020 01:06:52 |
| User entered '16 Sep 2020 18:06'                                                                                                                                                                                                                               | System | 17 Sep 2020 01:06:52 |



US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 17:29' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 2' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:33:55', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1fd24be6-f3ab-4bf9-a5ff-465c4f5e6afa' | System | 18 Sep 2020 01:34:18 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 01:34:18 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1fd24be6-f3ab-4bf9-a5ff-465c4f5e6afa' | System | 18 Sep 2020 01:34:18 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 18 Sep 2020 01:34:18 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:05', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1fd24be6-f3ab-4bf9-a5ff-465c4f5e6afa' | System | 18 Sep 2020 01:34:18 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 18 Sep 2020 01:34:18 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:10', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1fd24be6-f3ab-4bf9-a5ff-465c4f5e6afa' | System | 18 Sep 2020 01:34:18 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 01:34:18 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:13', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '1fd24be6-f3ab-4bf9-a5ff-465c4f5e6afa' | System | 18 Sep 2020 01:34:18 |
| User entered '17 Sep 2020 18:34'                                                                                                                                                                                                                               | System | 18 Sep 2020 01:34:18 |



US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 3' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ad1dc21b-6e84-46f0-82d5-829214c0d9c2' | System | 19 Sep 2020 01:42:02 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 01:42:02 |

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:31:59

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ad1dc21b-6e84-46f0-82d5-829214c0d9c2' | System | 19 Sep 2020 01:42:02 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Sep 2020 01:42:02 |

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:50', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ad1dc21b-6e84-46f0-82d5-829214c0d9c2' | System | 19 Sep 2020 01:42:02 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Sep 2020 01:42:02 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:56', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ad1dc21b-6e84-46f0-82d5-829214c0d9c2' | System | 19 Sep 2020 01:42:02 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 01:42:02 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:59', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ad1dc21b-6e84-46f0-82d5-829214c0d9c2' | System | 19 Sep 2020 01:42:02 |
| User entered '18 Sep 2020 18:41'                                                                                                                                                                                                                               | System | 19 Sep 2020 01:42:02 |



US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 4' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:09', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ddfb13c-28bc-4adf-9008-760d1964fc37' | System | 20 Sep 2020 02:35:30 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 02:35:30 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:14', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ddfb13c-28bc-4adf-9008-760d1964fc37' | System | 20 Sep 2020 02:35:30 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Sep 2020 02:35:30 |

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:19', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ddfb13c-28bc-4adf-9008-760d1964fc37' | System | 20 Sep 2020 02:35:30 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Sep 2020 02:35:30 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:23', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ddfb13c-28bc-4adf-9008-760d1964fc37' | System | 20 Sep 2020 02:35:30 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 02:35:30 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:26', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9ddfb13c-28bc-4adf-9008-760d1964fc37' | System | 20 Sep 2020 02:35:30 |
| User entered '19 Sep 2020 19:35'                                                                                                                                                                                                                               | System | 20 Sep 2020 02:35:30 |



US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 5' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:26:46', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '73ec5043-9c6a-4e7f-8946-6b6f36015bc2' | System | 21 Sep 2020 00:27:07 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 21 Sep 2020 00:27:07 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:26:50', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '73ec5043-9c6a-4e7f-8946-6b6f36015bc2' | System | 21 Sep 2020 00:27:07 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Sep 2020 00:27:07 |

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:26:54', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '73ec5043-9c6a-4e7f-8946-6b6f36015bc2' | System | 21 Sep 2020 00:27:07 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Sep 2020 00:27:07 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '73ec5043-9c6a-4e7f-8946-6b6f36015bc2' | System | 21 Sep 2020 00:27:07 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 21 Sep 2020 00:27:07 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:03', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '73ec5043-9c6a-4e7f-8946-6b6f36015bc2' | System | 21 Sep 2020 00:27:07 |
| User entered '20 Sep 2020 17:27'                                                                                                                                                                                                                               | System | 21 Sep 2020 00:27:07 |



US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 6' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:04', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '36824927-a550-4ebd-9ed3-6aa393fd2f20' | System | 22 Sep 2020 01:24:25 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 01:24:25 |

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:31:59

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:10', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '36824927-a550-4ebd-9ed3-6aa393fd2f20' | System | 22 Sep 2020 01:24:25 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Sep 2020 01:24:25 |

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:13', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '36824927-a550-4ebd-9ed3-6aa393fd2f20' | System | 22 Sep 2020 01:24:25 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Sep 2020 01:24:25 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:16', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '36824927-a550-4ebd-9ed3-6aa393fd2f20' | System | 22 Sep 2020 01:24:25 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 01:24:25 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:20', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '36824927-a550-4ebd-9ed3-6aa393fd2f20' | System | 22 Sep 2020 01:24:25 |
| User entered '21 Sep 2020 18:24'                                                                                                                                                                                                                               | System | 22 Sep 2020 01:24:25 |



US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 7' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:23:39', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7e9f6cfd-7e5b-4cbc-ae56-2e3e967cb75b' | System | 23 Sep 2020 00:24:08 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 00:24:08 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:23:54', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7e9f6cfd-7e5b-4cbc-ae56-2e3e967cb75b' | System | 23 Sep 2020 00:24:08 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Sep 2020 00:24:08 |

US3462255

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:31:59

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:23:58', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7e9f6cfd-7e5b-4cbc-ae56-2e3e967cb75b' | System | 23 Sep 2020 00:24:08 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Sep 2020 00:24:08 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7e9f6cfd-7e5b-4cbc-ae56-2e3e967cb75b' | System | 23 Sep 2020 00:24:08 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 00:24:08 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:04', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '7e9f6cfd-7e5b-4cbc-ae56-2e3e967cb75b' | System | 23 Sep 2020 00:24:08 |
| User entered '22 Sep 2020 17:24'                                                                                                                                                                                                                               | System | 23 Sep 2020 00:24:08 |



US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '95558f1c-a426-4296-8552-ba823f0685da' User entered 'None (0)' | System | 16 Sep 2020 21:22:06 |
|                                                                                                                                                                                                                                                                                        | System | 16 Sep 2020 21:22:06 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:39', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '95558f1c-a426-4296-8552-ba823f0685da' User entered 'None (0)' | System | 16 Sep 2020 21:22:06 |
|                                                                                                                                                                                                                                                                                        | System | 16 Sep 2020 21:22:06 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:43', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '95558f1c-a426-4296-8552-ba823f0685da' User entered 'None (0)' | System | 16 Sep 2020 21:22:06 |
|                                                                                                                                                                                                                                                                                        | System | 16 Sep 2020 21:22:06 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:47', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '95558f1c-a426-4296-8552-ba823f0685da' User entered 'None (0)' | System | 16 Sep 2020 21:22:06 |
|                                                                                                                                                                                                                                                                                        | System | 16 Sep 2020 21:22:06 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:51', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '95558f1c-a426-4296-8552-ba823f0685da' User entered 'None (0)' | System | 16 Sep 2020 21:22:06 |
|                                                                                                                                                                                                                                                                                        | System | 16 Sep 2020 21:22:06 |



US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:54', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '95558f1c-a426-4296-8552-ba823f0685da' User entered 'None (0)' | System | 16 Sep 2020 21:22:06 |
|                                                                                                                                                                                                                                                                                        | System | 16 Sep 2020 21:22:06 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:31:59

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:21:59', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '95558f1c-a426-4296-8552-ba823f0685da' | System | 16 Sep 2020 21:22:06 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 16 Sep 2020 21:22:06 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T14:22:03', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '95558f1c-a426-4296-8552-ba823f0685da' User entered '16 Sep 2020 14:22' | System | 16 Sep 2020 21:22:06 |
|                                                                                                                                                                                                                                                                                                 | System | 16 Sep 2020 21:22:06 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 14:04' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 16:34' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 1, after vaccination (at home)' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:07:06', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fefdb301-c8f3-4be6-abf8-5033d09ef51f' | System | 17 Sep 2020 01:08:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 17 Sep 2020 01:08:08 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:07:23', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fefdb301-c8f3-4be6-abf8-5033d09ef51f' | System | 17 Sep 2020 01:08:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 17 Sep 2020 01:08:08 |



US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:07:27', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fefdb301-c8f3-4be6-abf8-5033d09ef51f' User entered 'None (0)' | System | 17 Sep 2020 01:08:08 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:07:34', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fefdb301-c8f3-4be6-abf8-5033d09ef51f' | System | 17 Sep 2020 01:08:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 17 Sep 2020 01:08:08 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:07:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fefdb301-c8f3-4be6-abf8-5033d09ef51f' | System | 17 Sep 2020 01:08:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 17 Sep 2020 01:08:08 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:31:59

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:07:44', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fefdb301-c8f3-4be6-abf8-5033d09ef51f' | System | 17 Sep 2020 01:08:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 17 Sep 2020 01:08:08 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:08:01', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fefdb301-c8f3-4be6-abf8-5033d09ef51f' User entered 'No (N)' | System | 17 Sep 2020 01:08:08 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-16T18:08:04', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'fefdb301-c8f3-4be6-abf8-5033d09ef51f' User entered '16 Sep 2020 18:08' | System | 17 Sep 2020 01:08:08 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 17:29' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |



US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 2' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:19', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25b816c6-9f34-46fa-be43-e48e83bc6372' | System | 18 Sep 2020 01:34:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 01:34:52 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:23', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25b816c6-9f34-46fa-be43-e48e83bc6372' | System | 18 Sep 2020 01:34:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 01:34:52 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:28', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25b816c6-9f34-46fa-be43-e48e83bc6372' | System | 18 Sep 2020 01:34:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 01:34:52 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:33', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25b816c6-9f34-46fa-be43-e48e83bc6372' | System | 18 Sep 2020 01:34:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 01:34:52 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25b816c6-9f34-46fa-be43-e48e83bc6372' | System | 18 Sep 2020 01:34:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 01:34:52 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25b816c6-9f34-46fa-be43-e48e83bc6372' | System | 18 Sep 2020 01:34:52 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 18 Sep 2020 01:34:52 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:31:59

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:45', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25b816c6-9f34-46fa-be43-e48e83bc6372' | System | 18 Sep 2020 01:34:52 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 18 Sep 2020 01:34:52 |



US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-17T18:34:47', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '25b816c6-9f34-46fa-be43-e48e83bc6372' | System | 18 Sep 2020 01:34:52 |
| User entered '17 Sep 2020 18:34'                                                                                                                                                                                                                               | System | 18 Sep 2020 01:34:52 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 3' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:07', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b9eb334e-f694-410e-be05-3d3933232f93' | System | 19 Sep 2020 01:41:38 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 01:41:38 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:10', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b9eb334e-f694-410e-be05-3d3933232f93' | System | 19 Sep 2020 01:41:38 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 01:41:38 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:16', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b9eb334e-f694-410e-be05-3d3933232f93' | System | 19 Sep 2020 01:41:38 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 01:41:38 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:22', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b9eb334e-f694-410e-be05-3d3933232f93' | System | 19 Sep 2020 01:41:38 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 01:41:38 |



US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:24', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b9eb334e-f694-410e-be05-3d3933232f93' | System | 19 Sep 2020 01:41:38 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 01:41:38 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

CHILLS

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:27', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b9eb334e-f694-410e-be05-3d3933232f93' | System | 19 Sep 2020 01:41:38 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 19 Sep 2020 01:41:38 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:31:59

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:31', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b9eb334e-f694-410e-be05-3d3933232f93' | System | 19 Sep 2020 01:41:38 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Sep 2020 01:41:38 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-18T18:41:34', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'b9eb334e-f694-410e-be05-3d3933232f93' | System | 19 Sep 2020 01:41:38 |
| User entered '18 Sep 2020 18:41'                                                                                                                                                                                                                               | System | 19 Sep 2020 01:41:38 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 4' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:38', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '202258f4-8353-49af-8fff-7cf0c5ea89f2' | System | 20 Sep 2020 02:36:09 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 02:36:09 |



US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:43', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '202258f4-8353-49af-8fff-7cf0c5ea89f2' | System | 20 Sep 2020 02:36:09 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 02:36:09 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:48', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '202258f4-8353-49af-8fff-7cf0c5ea89f2' | System | 20 Sep 2020 02:36:09 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 02:36:09 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:51', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '202258f4-8353-49af-8fff-7cf0c5ea89f2' | System | 20 Sep 2020 02:36:09 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 02:36:09 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:53', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '202258f4-8353-49af-8fff-7cf0c5ea89f2' | System | 20 Sep 2020 02:36:09 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 02:36:09 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:35:56', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '202258f4-8353-49af-8fff-7cf0c5ea89f2' | System | 20 Sep 2020 02:36:09 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 20 Sep 2020 02:36:09 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:31:59

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:36:02', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '202258f4-8353-49af-8fff-7cf0c5ea89f2' | System | 20 Sep 2020 02:36:09 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 20 Sep 2020 02:36:09 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-19T19:36:05', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '202258f4-8353-49af-8fff-7cf0c5ea89f2' | System | 20 Sep 2020 02:36:09 |
| User entered '19 Sep 2020 19:36'                                                                                                                                                                                                                               | System | 20 Sep 2020 02:36:09 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |



US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 5' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:09', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f8fe2628-267a-4361-bcbc-fd172411d040' | System | 21 Sep 2020 00:27:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Sep 2020 00:27:44 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:15', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f8fe2628-267a-4361-bcbc-fd172411d040' | System | 21 Sep 2020 00:27:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Sep 2020 00:27:44 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:19', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f8fe2628-267a-4361-bcbc-fd172411d040' | System | 21 Sep 2020 00:27:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Sep 2020 00:27:44 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:24', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f8fe2628-267a-4361-bcbc-fd172411d040' | System | 21 Sep 2020 00:27:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Sep 2020 00:27:44 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:27', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f8fe2628-267a-4361-bcbc-fd172411d040' | System | 21 Sep 2020 00:27:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Sep 2020 00:27:44 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:30', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f8fe2628-267a-4361-bcbc-fd172411d040' | System | 21 Sep 2020 00:27:44 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 21 Sep 2020 00:27:44 |



US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f8fe2628-267a-4361-bcbc-fd172411d040' | System | 21 Sep 2020 00:27:44 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 21 Sep 2020 00:27:44 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:31:59

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-20T17:27:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'f8fe2628-267a-4361-bcbc-fd172411d040' | System | 21 Sep 2020 00:27:44 |
| User entered '20 Sep 2020 17:27'                                                                                                                                                                                                                               | System | 21 Sep 2020 00:27:44 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 6' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:26', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ce7bd2fc-2314-443e-9935-5598070749ec' | System | 22 Sep 2020 01:25:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 01:25:08 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:28', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ce7bd2fc-2314-443e-9935-5598070749ec' User entered 'None (0)' | System | 22 Sep 2020 01:25:08 |
|                                                                                                                                                                                                                                                                                        | System | 22 Sep 2020 01:25:08 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:31', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ce7bd2fc-2314-443e-9935-5598070749ec' | System | 22 Sep 2020 01:25:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 01:25:08 |



US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:33', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ce7bd2fc-2314-443e-9935-5598070749ec' User entered 'None (0)' | System | 22 Sep 2020 01:25:08 |
|                                                                                                                                                                                                                                                                                        | System | 22 Sep 2020 01:25:08 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:36', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ce7bd2fc-2314-443e-9935-5598070749ec' | System | 22 Sep 2020 01:25:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 01:25:08 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:38', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ce7bd2fc-2314-443e-9935-5598070749ec' | System | 22 Sep 2020 01:25:08 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 22 Sep 2020 01:25:08 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:31:59

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:42', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ce7bd2fc-2314-443e-9935-5598070749ec' | System | 22 Sep 2020 01:25:08 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 22 Sep 2020 01:25:08 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-21T18:24:44', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'ce7bd2fc-2314-443e-9935-5598070749ec' | System | 22 Sep 2020 01:25:08 |
| User entered '21 Sep 2020 18:24'                                                                                                                                                                                                                               | System | 22 Sep 2020 01:25:08 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 16 Sep 2020 21:06:05 |
| User entered 'Day 7' | System | 16 Sep 2020 21:06:05 |



US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:12', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'a4c80bee-c488-4e0c-af82-7b8611e9c287' | System | 23 Sep 2020 00:24:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 00:24:39 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:14', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'a4c80bee-c488-4e0c-af82-7b8611e9c287' | System | 23 Sep 2020 00:24:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 00:24:39 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:17', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'a4c80bee-c488-4e0c-af82-7b8611e9c287' | System | 23 Sep 2020 00:24:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 00:24:39 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:19', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'a4c80bee-c488-4e0c-af82-7b8611e9c287' | System | 23 Sep 2020 00:24:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 00:24:39 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:23', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'a4c80bee-c488-4e0c-af82-7b8611e9c287' | System | 23 Sep 2020 00:24:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 00:24:39 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:25', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'a4c80bee-c488-4e0c-af82-7b8611e9c287' | System | 23 Sep 2020 00:24:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 23 Sep 2020 00:24:39 |

US3462255

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:31:59

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:31', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'a4c80bee-c488-4e0c-af82-7b8611e9c287' | System | 23 Sep 2020 00:24:39 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Sep 2020 00:24:39 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-09-22T17:24:34', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: 'a4c80bee-c488-4e0c-af82-7b8611e9c287' | System | 23 Sep 2020 00:24:39 |
| User entered '22 Sep 2020 17:24'                                                                                                                                                                                                                               | System | 23 Sep 2020 00:24:39 |



US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 12:00' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:31:59**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 16 Sep 2020 21:06:05 |

US3462255

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Was Contact Attempted?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:10:55 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered '23 Sep 2020' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:10:55 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:10:55 |
|                                            |                       |                      |
|                                            |                       |                      |

US3462255

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 01:10:55 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:11:12 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Nov 2020 01:11:12 |



US3462255

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Was Contact Attempted?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:11:30 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered '30 Sep 2020' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:11:30 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:11:30 |
|                                            |                       |                      |
|                                            |                       |                      |

US3462255

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 01:11:30 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:11:42 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Nov 2020 01:11:42 |

US3462255

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Was Contact Attempted?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:11:53 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered '07 Oct 2020' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:11:53 |
|                            |                       |                      |
|                            |                       |                      |



US3462255

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:11:53 |
|                                            |                       |                      |
|                                            |                       |                      |

US3462255

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 01:11:53 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:12:04 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Nov 2020 01:12:04 |

US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:31:59**

[Was this visit performed?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:12:21 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered '14 Oct 2020' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:12:21 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:59

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

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| User entered 'Clinic (Clinic)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:12:21 |
|                                |                       |                      |
|                                |                       |                      |

US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:31:59**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 06 Nov 2020 01:12:21 |



US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:59

[Were vital signs assessed?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:12:54 |
|                       |                       |                      |
|                       |                       |                      |

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:59

Date of assessment (*dd MMM yyyy*)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 01:12:54 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

[Time of assessment \(00:00-23:59\)](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 01:12:54 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 01:12:54 |

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:59

Temperature (xxx.x)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 01:12:54 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder:** Visit 3 Day 57 (1)

**Form:** Vital Signs

**Generated On:** 26 Nov 2020 09:31:59

[Route of measurement](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 01:12:54 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:59

[If Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 01:12:54 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:59

[Pulse \(xxx\)](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 01:12:54 |
|                     |                       |                      |
|                     |                       |                      |



US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 01:12:54 |

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:59

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

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 01:12:54 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

[Respiratory Rate units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 01:12:54 |

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:59

Systolic Blood Pressure (xxx)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 01:12:54 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 01:12:54 |

US3462255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:59

Diastolic Blood Pressure (xxx)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 01:12:54 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:31:59**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 01:12:54 |

US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:31:59**

[Was the physical examination performed?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:12:59 |
|                       |                       |                      |
|                       |                       |                      |



US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 01:12:59 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:31:59**

[Was the sample collected?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:13:14 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered '14 Oct 2020' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:13:14 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:31:59**

[Collection time \(00:00-23:59\)](#)

| Audit                | User                  | Time (GMT)           |
|----------------------|-----------------------|----------------------|
| User entered '13:40' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:13:14 |
|                      |                       |                      |
|                      |                       |                      |

US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Oct 2020 13:40' | System | 06 Nov 2020 01:13:14 |

US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 06 Nov 2020 01:13:18 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Nov 2020 01:13:18 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 64' | System | 19 Aug 2020 21:54:26 |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-19T08:09:08', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3fe63411-dff8-4b0f-bc36-02b4f9a0cc83' User entered 'Yes (Y)' | System | 19 Oct 2020 15:11:03 |
|                                                                                                                                                                                                                                                                                       | System | 19 Oct 2020 15:11:03 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

Have you been exposed to someone with 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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-19T08:09:30', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3fe63411-dff8-4b0f-bc36-02b4f9a0cc83' | System | 19 Oct 2020 15:11:03 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Oct 2020 15:11:03 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-19T08:09:45', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3fe63411-dff8-4b0f-bc36-02b4f9a0cc83' | System | 19 Oct 2020 15:11:03 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 19 Oct 2020 15:11:03 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-19T08:09:58', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3fe63411-dff8-4b0f-bc36-02b4f9a0cc83' | System | 19 Oct 2020 15:11:03 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 19 Oct 2020 15:11:03 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-19T08:10:17', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3fe63411-dff8-4b0f-bc36-02b4f9a0cc83' | System | 19 Oct 2020 15:11:03 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'                                                                                                                                                               | System | 19 Oct 2020 15:11:03 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-19T08:10:24', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '3fe63411-dff8-4b0f-bc36-02b4f9a0cc83' User entered '19 Oct 2020 08:10:24' | System | 19 Oct 2020 15:11:03 |
|                                                                                                                                                                                                                                                                                                    | System | 19 Oct 2020 15:11:03 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 19 Aug 2020 21:54:26 |
| User entered '19 Oct 2020 00:01' | System | 19 Aug 2020 21:54:26 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 19 Aug 2020 21:54:26 |
| User entered '23 Oct 2020 23:59' | System | 19 Aug 2020 21:54:26 |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 71' | System | 19 Aug 2020 21:54:26 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-28T12:02:00', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9da81764-7151-46dd-952d-4f9299bcb2a2' User entered 'No (N)' | System | 28 Oct 2020 19:02:20 |
|                                                                                                                                                                                                                                                                                      | System | 28 Oct 2020 19:02:20 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

Have you been exposed to someone with 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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-28T12:02:06', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9da81764-7151-46dd-952d-4f9299bcb2a2' | System | 28 Oct 2020 19:02:20 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 28 Oct 2020 19:02:20 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-10-28T12:02:17', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '9da81764-7151-46dd-952d-4f9299bcb2a2' User entered '28 Oct 2020 12:02:17' | System | 28 Oct 2020 19:02:20 |
|                                                                                                                                                                                                                                                                                                    | System | 28 Oct 2020 19:02:20 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 19 Aug 2020 21:54:26 |
| User entered '26 Oct 2020 00:01' | System | 19 Aug 2020 21:54:26 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 19 Aug 2020 21:54:26 |
| User entered '30 Oct 2020 23:59' | System | 19 Aug 2020 21:54:26 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 19 Aug 2020 21:54:26 |
| User entered 'Day 78' | System | 19 Aug 2020 21:54:26 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-11-02T03:44:35', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '15766665-e07a-4e27-801b-948695b7ea50' | System | 02 Nov 2020 11:45:00 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Nov 2020 11:45:00 |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

Have you been exposed to someone with 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 (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-11-02T03:44:44', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '15766665-e07a-4e27-801b-948695b7ea50' | System | 02 Nov 2020 11:45:00 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Nov 2020 11:45:00 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5316D3BF-D092-49CF-8764-EC664CF2B7E5)', Time: '2020-11-02T03:44:56', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '15766665-e07a-4e27-801b-948695b7ea50' | System | 02 Nov 2020 11:45:00 |
| User entered '02 Nov 2020 03:44:56'                                                                                                                                                                                                                            | System | 02 Nov 2020 11:45:00 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 19 Aug 2020 21:54:26 |
| User entered '02 Nov 2020 00:01' | System | 19 Aug 2020 21:54:26 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 19 Aug 2020 21:54:26 |
| User entered '06 Nov 2020 23:59' | System | 19 Aug 2020 21:54:26 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 61' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '16 Oct 2020 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '20 Oct 2020 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 68' | System | 19 Nov 2020 23:21:32 |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '23 Oct 2020 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '27 Oct 2020 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 75' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '30 Oct 2020 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '03 Nov 2020 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 82' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '06 Nov 2020 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '10 Nov 2020 23:59' | System | 19 Nov 2020 23:21:32 |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '13 Nov 2020 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '17 Nov 2020 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-11-23T14:53:32', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2a9230cc-5cbe-44a0-b6dc-eb4092210f65' | System | 23 Nov 2020 22:53:50 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Nov 2020 22:53:50 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

Have you been exposed to someone with 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 (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-11-23T14:53:40', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2a9230cc-5cbe-44a0-b6dc-eb4092210f65' | System | 23 Nov 2020 22:53:50 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 23 Nov 2020 22:53:50 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72867651-5397-45B5-A1B3-DC480189F49B)', Time: '2020-11-23T14:53:45', User OID: 'PatientReportedOutcome (US3462255)', ODM File OID: '2a9230cc-5cbe-44a0-b6dc-eb4092210f65' User entered '23 Nov 2020 14:53:45' | System | 23 Nov 2020 22:53:50 |
|                                                                                                                                                                                                                                                                                                    | System | 23 Nov 2020 22:53:50 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '20 Nov 2020 00:01' | System | 19 Nov 2020 23:21:32 |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '24 Nov 2020 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '27 Nov 2020 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '01 Dec 2020 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '04 Dec 2020 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '08 Dec 2020 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 23:21:32 |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '11 Dec 2020 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '15 Dec 2020 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '18 Dec 2020 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '22 Dec 2020 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '25 Dec 2020 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '29 Dec 2020 23:59' | System | 19 Nov 2020 23:21:32 |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '01 Jan 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '05 Jan 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '08 Jan 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '12 Jan 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '15 Jan 2021 00:01' | System | 19 Nov 2020 23:21:32 |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '19 Jan 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '22 Jan 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '26 Jan 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '29 Jan 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '02 Feb 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 23:21:32 |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '05 Feb 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '09 Feb 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '12 Feb 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '16 Feb 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '19 Feb 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '23 Feb 2021 23:59' | System | 19 Nov 2020 23:21:32 |



US3462255

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '26 Feb 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '02 Mar 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '05 Mar 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '09 Mar 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '12 Mar 2021 00:01' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '16 Mar 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '19 Mar 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '23 Mar 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '26 Mar 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '30 Mar 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '02 Apr 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '06 Apr 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '09 Apr 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '13 Apr 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '16 Apr 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '20 Apr 2021 23:59' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '23 Apr 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '27 Apr 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '30 Apr 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '04 May 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '07 May 2021 00:01' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '11 May 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '14 May 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '18 May 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '21 May 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '25 May 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '28 May 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '01 Jun 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '04 Jun 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '08 Jun 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '11 Jun 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '15 Jun 2021 23:59' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '18 Jun 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '22 Jun 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '25 Jun 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '29 Jun 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '02 Jul 2021 00:01' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '06 Jul 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '09 Jul 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '13 Jul 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '16 Jul 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '20 Jul 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '23 Jul 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '27 Jul 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '30 Jul 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '03 Aug 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '06 Aug 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '10 Aug 2021 23:59' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '13 Aug 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '17 Aug 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '20 Aug 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '24 Aug 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '27 Aug 2021 00:01' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '31 Aug 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '03 Sep 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '07 Sep 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '10 Sep 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '14 Sep 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '17 Sep 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '21 Sep 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '24 Sep 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '28 Sep 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '01 Oct 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '05 Oct 2021 23:59' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '08 Oct 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '12 Oct 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '15 Oct 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '19 Oct 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '22 Oct 2021 00:01' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '26 Oct 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '29 Oct 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '02 Nov 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '05 Nov 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '09 Nov 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '12 Nov 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '16 Nov 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '19 Nov 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '23 Nov 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '26 Nov 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '30 Nov 2021 23:59' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '03 Dec 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '07 Dec 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '10 Dec 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '14 Dec 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '17 Dec 2021 00:01' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '21 Dec 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '24 Dec 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '28 Dec 2021 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '31 Dec 2021 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '04 Jan 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '07 Jan 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '11 Jan 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '14 Jan 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '18 Jan 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '21 Jan 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '25 Jan 2022 23:59' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '28 Jan 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '01 Feb 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '04 Feb 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '08 Feb 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '11 Feb 2022 00:01' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '15 Feb 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '18 Feb 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '22 Feb 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '25 Feb 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '01 Mar 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '04 Mar 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '08 Mar 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '11 Mar 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '15 Mar 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '18 Mar 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '22 Mar 2022 23:59' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '25 Mar 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '29 Mar 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '01 Apr 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '05 Apr 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '08 Apr 2022 00:01' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '12 Apr 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '15 Apr 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '19 Apr 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '22 Apr 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '26 Apr 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '29 Apr 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '03 May 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '06 May 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '10 May 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '13 May 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '17 May 2022 23:59' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '20 May 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '24 May 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '27 May 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '31 May 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '03 Jun 2022 00:01' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '07 Jun 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '10 Jun 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '14 Jun 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '17 Jun 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '21 Jun 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '24 Jun 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '28 Jun 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '01 Jul 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '05 Jul 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '08 Jul 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '12 Jul 2022 23:59' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '15 Jul 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '19 Jul 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '22 Jul 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '26 Jul 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '29 Jul 2022 00:01' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '02 Aug 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '05 Aug 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '09 Aug 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '12 Aug 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '16 Aug 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '19 Aug 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '23 Aug 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '26 Aug 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '30 Aug 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '02 Sep 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '06 Sep 2022 23:59' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '09 Sep 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '13 Sep 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '16 Sep 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '20 Sep 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '23 Sep 2022 00:01' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '27 Sep 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '30 Sep 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '04 Oct 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '07 Oct 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '11 Oct 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 23:21:32 |



US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '14 Oct 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '18 Oct 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '21 Oct 2022 00:01' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:31:59**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 23:21:32 |
| Amendment Manager: User entered '25 Oct 2022 23:59' | System | 19 Nov 2020 23:21:32 |

US3462255

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Was Contact Attempted?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 17 Nov 2020 19:15:53 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User entered '13 Nov 2020' | Danuel Hamlin (b) (4) | 17 Nov 2020 19:15:53 |
|                            |                       |                      |
|                            |                       |                      |

US3462255

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Danuel Hamlin (b) (4) | 17 Nov 2020 19:15:53 |
|                                            |                       |                      |
|                                            |                       |                      |



US3462255

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:31:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| User entered empty. | Danuel Hamlin (b) (4) | 17 Nov 2020 19:15:53 |
|                     |                       |                      |
|                     |                       |                      |

US3462255

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 17 Nov 2020 19:16:52 |
|                        |                       |                      |
|                        |                       |                      |

US3462255

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:31:59**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Nov 2020 19:16:52 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events Summary

**Generated On:** 26 Nov 2020 09:31:59

[Did the participant experience any adverse events?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 17 Nov 2020 21:44:31 |
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:11:38 |

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:59

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 22:25:53 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 21 Oct 2020 21:06:06 |
| User entered<br>'USA-US093-2020-mRNA-1273-P301000008' | System           | 21 Oct 2020 21:06:01 |
| User entered 'New'                                    | (b) (4), (b) (6) | 21 Oct 2020 21:06:01 |

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:59

[Adverse event](#)

| Audit                                                                                                                                                                                                          | User                                        | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                            | (b) (4), (b) (6)                            | 17 Nov 2020 22:37:16 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)             | 21 Oct 2020 00:22:28 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                   | Coder Import (b) (4)<br>(b) (4)             | 21 Oct 2020 00:22:28 |
| Data point term sent to Coder                                                                                                                                                                                  | System                                      | 21 Oct 2020 00:21:11 |
| User entered 'Dehydration'                                                                                                                                                                                     | Danuel Hamlin (b) (4)<br>(b) (4)<br>(b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Was this a medically-attended AE?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 17 Nov 2020 22:37:26 |
| DataPoint Un-verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:37:21 |
| DataPoint Verified.    | (b) (4), (b) (6)      | 17 Nov 2020 22:37:19 |
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 22:37:23 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |



US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 22:37:28 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:59

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | (b) (4), (b) (6)      | 17 Nov 2020 22:37:31 |
| User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. Per narrative, symptoms of fatigue and malaise began approximately one week prior to onset of events. (Onset of events: 16 Oct 2020) If not updating the start date, please clarify.' (Site from Safety).                                                                                                                                                                               | (b) (4), (b) (6)      | 07 Nov 2020 00:14:06 |
| Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. Per narrative, symptoms of fatigue and malaise began approximately one week prior to onset of events. (Onset of events: 16 Oct 2020) If not updating the start date, please clarify.' answered with 'Subject had mild symptoms of fatigue and general weakness 1 week prior to hospitalization, however, no diagnosis of dehydration or anemia until date of hospitalization. ' (Site from Safety). | Danuel Hamlin (b) (4) | 06 Nov 2020 00:13:12 |
| User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. Per narrative, symptoms of fatigue and malaise began approximately one week prior to onset of events. (Onset of events: 16 Oct 2020) If not updating the start date, please clarify.' (Site from Safety).                                                                                                                                                                               | (b) (4), (b) (6)      | 30 Oct 2020 22:58:23 |
| User entered '16 Oct 2020'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:59

Start time (00:00-23:59)

| Audit                                                                                                                                                                                             | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                               | (b) (4), (b) (6)      | 17 Nov 2020 22:37:37 |
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                                            | (b) (4), (b) (6)      | 12 Nov 2020 15:06:21 |
| Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Confirmed. Start date/time is correct.' (Site from System). | Danuel Hamlin (b) (4) | 21 Oct 2020 00:21:40 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                                            | System                | 21 Oct 2020 00:20:55 |
| User entered '08:00'                                                                                                                                                                              | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:31:59**

[AE start date and time \(derived\)](#)

| Audit                                                                                                                                                                                                                   | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User opened query 'PV Query: As fatigue and weakness are symptoms of dehydration and anemia, please update start date for events of dehydration and anemia to date of onset of signs and symptoms.' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 20:53:14 |
| User entered '16 Oct 2020 08:00'                                                                                                                                                                                        | System           | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Ongoing?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 22:37:40 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

If not Ongoing, end date (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 17 Nov 2020 22:37:42 |
| User entered '17 Oct 2020' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:59

[End time \(00:00-23:59\)](#)

| Audit                                                                                                                                                                             | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                               | (b) (4), (b) (6)      | 17 Nov 2020 22:37:45 |
| User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).                                | (b) (4), (b) (6)      | 13 Nov 2020 15:37:43 |
| Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'Confirmed. Time is correct' (Site from System). | Danuel Hamlin (b) (4) | 21 Oct 2020 00:21:50 |
| User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).                                | System                | 21 Oct 2020 00:20:55 |
| User entered '12:00'                                                                                                                                                              | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[AE End Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Oct 2020 12:00' | System | 21 Oct 2020 00:20:55 |



US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Severity](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)      | 17 Nov 2020 22:37:49 |
| User entered 'Grade 4 (Grade 4)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Is the adverse event serious?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 17 Nov 2020 22:37:54 |
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:59

[Death](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:37:56 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Life threatening](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:38:01 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:37:59 |
| User entered '1'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 17 Nov 2020 22:38:03 |
| User entered '16 Oct 2020' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 17 Nov 2020 22:38:05 |
| User entered '17 Oct 2020' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Admitted to ICU?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 22:38:07 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |



US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Number of Days in ICU](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:38:39 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Persistent or significant disability or incapacity](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:38:42 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Congenital anomaly or birth defect](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:38:44 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Other medically important event](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:38:50 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Relationship to investigational product](#)

| Audit                                    | User                  | Time (GMT)           |
|------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)      | 17 Nov 2020 22:38:52 |
| User entered 'Not Related (NOT RELATED)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Relationship to Study Procedure](#)

| Audit                                    | User                  | Time (GMT)           |
|------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)      | 17 Nov 2020 22:38:55 |
| User entered 'Not Related (NOT RELATED)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Action taken with investigational product](#)

| Audit                                          | User                  | Time (GMT)           |
|------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)      | 17 Nov 2020 22:38:58 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:59

[None](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:39:03 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |



US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:59

[Concomitant Medication](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:39:05 |
| User entered '1'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Concomitant Procedure](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:39:07 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Outcome](#)

| Audit                                                  | User                  | Time (GMT)           |
|--------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)      | 17 Nov 2020 22:39:09 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:39:11 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:59

[Narrative](#)

| Audit                                                                                                                                                                                                                                        | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                          | (b) (4), (b) (6)      | 17 Nov 2020 22:39:16 |
| User opened query 'PV Query: Please provide the etiology of the dehydration and anemia.' (Site from Safety).                                                                                                                                 | (b) (4), (b) (6)      | 13 Nov 2020 20:52:54 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).                                                               | (b) (4), (b) (6)      | 13 Nov 2020 20:52:38 |
| User closed query 'PV Query: Please provide the etiology of the dehydration and anemia.' (Site from Safety).                                                                                                                                 | (b) (4), (b) (6)      | 07 Nov 2020 00:13:06 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).                                                               | (b) (4), (b) (6)      | 07 Nov 2020 00:12:55 |
| Query 'PV Query: Please provide the etiology of the dehydration and anemia.' answered with 'Pending receipt of outside medical records. ' (Site from Safety).                                                                                | Danuel Hamlin (b) (4) | 06 Nov 2020 00:13:54 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Pending receipt of outside medical records from hospital.' (Site from Safety). | Danuel Hamlin (b) (4) | 06 Nov 2020 00:13:44 |
| User opened query 'PV Query: Please provide the etiology of the dehydration and anemia.' (Site from Safety).                                                                                                                                 | (b) (4), (b) (6)      | 30 Oct 2020 22:58:36 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).                                                               | (b) (4), (b) (6)      | 30 Oct 2020 22:58:02 |

US3462255

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User entered '57 year old female with hypertension, type II diabetes, GERD, and history of gastric bypass surgery on 02OCT2020. Subject woke up 16OCT2020 with increased fatigue and malaise. Those symptoms had been ongoing for approximately one week prior, but suddenly worsened. Subject went to Emergency Department morning of 16OCT2020 at approximately 09:30 and was diagnosed with severe dehydration and anemia. Subject was treated with IV fluids and iron supplementation. Subject was admitted to monitor kidney function. Symptoms improved with treatments. Subject was discharged 17OCT2020 at approximately 12:00 with instructions to take over the counter iron supplementation.' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Oct 2020 00:20:55 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Oct 2020 00:20:55 |



US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:31:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 21 Oct 2020 00:20:55 |

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:59

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 22:41:12 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 21 Oct 2020 21:12:58 |
| User entered<br>'USA-US093-2020-mRNA-1273-P301000008' | (b) (4), (b) (6) | 21 Oct 2020 21:06:46 |

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:59

[Adverse event](#)

| Audit                                                                                                                                                                                       | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                         | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0. | Coder Import (b) (4)  | 21 Oct 2020 00:25:30 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                | (b) (4)               | 21 Oct 2020 00:25:30 |
| Data point term sent to Coder                                                                                                                                                               | Coder Import (b) (4)  | 21 Oct 2020 00:25:30 |
| User entered 'Anemia'                                                                                                                                                                       | System                | 21 Oct 2020 00:24:16 |
|                                                                                                                                                                                             | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |
|                                                                                                                                                                                             |                       |                      |
|                                                                                                                                                                                             |                       |                      |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Was this a medically-attended AE?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:59

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | User                  | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User opened query 'PV Query: As fatigue and weakness are symptoms of dehydration and anemia, please update start date for events of dehydration and anemia to date of onset of signs and symptoms.' (Site from Safety).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)      | 13 Nov 2020 20:53:37 |
| User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. Per narrative, symptoms of fatigue and malaise began approximately one week prior to onset of events. (Onset of events: 16 Oct 2020) If not updating the start date, please clarify.' (Site from Safety).                                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)      | 07 Nov 2020 00:10:47 |
| Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. Per narrative, symptoms of fatigue and malaise began approximately one week prior to onset of events. (Onset of events: 16 Oct 2020) If not updating the start date, please clarify.' answered with 'Subject had mild symptoms of fatigue and general weakness 1 week prior to hospitalization, however, no diagnosis of dehydration or anemia until date of hospitalization. We will review outside medical records once received and PI can determine if start date should be changed. ' (Site from Safety). | Danuel Hamlin (b) (4) | 06 Nov 2020 00:15:57 |
| User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. Per narrative, symptoms of fatigue and malaise began approximately one week prior to onset of events. (Onset of events: 16 Oct 2020) If not updating the start date, please clarify.' (Site from Safety).                                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)      | 30 Oct 2020 22:59:15 |
| User entered '16 Oct 2020'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:59

Start time (00:00-23:59)

| Audit                                                                                                                                                                                 | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                   | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                                | (b) (4), (b) (6)      | 12 Nov 2020 15:06:07 |
| Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Confirmed. Time is correct' (Site from System). | Danuel Hamlin (b) (4) | 21 Oct 2020 00:24:57 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                                | System                | 21 Oct 2020 00:23:29 |
| User entered '08:00'                                                                                                                                                                  | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |



US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[AE start date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Oct 2020 08:00' | System | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Ongoing?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '17 Oct 2020' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:59

[End time \(00:00-23:59\)](#)

| Audit                                                                                                                                                              | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).                 | (b) (4), (b) (6)      | 12 Nov 2020 15:06:05 |
| Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'Confirmed. ' (Site from System). | Danuel Hamlin (b) (4) | 21 Oct 2020 00:25:03 |
| User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).                 | System                | 21 Oct 2020 00:23:29 |
| User entered '12:00'                                                                                                                                               | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[AE End Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Oct 2020 12:00' | System | 21 Oct 2020 00:23:29 |

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:59

[Severity](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'Grade 4 (Grade 4)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Is the adverse event serious?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Death](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |



US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Life threatening](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '1'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '16 Oct 2020' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '17 Oct 2020' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Admitted to ICU?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Number of Days in ICU](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Persistent or significant disability or incapacity](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Congenital anomaly or birth defect](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |



US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Other medically important event](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Relationship to investigational product](#)

| Audit                                    | User                  | Time (GMT)           |
|------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'Not Related (NOT RELATED)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Relationship to Study Procedure](#)

| Audit                                    | User                  | Time (GMT)           |
|------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'Not Related (NOT RELATED)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Action taken with investigational product](#)

| Audit                                          | User                  | Time (GMT)           |
|------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[None](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Concomitant Medication](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '1'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Concomitant Procedure](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Outcome](#)

| Audit                                                  | User                  | Time (GMT)           |
|--------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |



US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:59

[Narrative](#)

| Audit                                                                                                                                                                                                                           | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                             | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User opened query 'PV Query: Please provide the etiology of the dehydration and anemia.' (Site from Safety).                                                                                                                    | (b) (4), (b) (6)      | 13 Nov 2020 20:53:50 |
| User closed query 'PV Query: Please report if the subject had any prior history of anemia, or risk factors for developing anemia.' (Site from Safety).                                                                          | (b) (4), (b) (6)      | 07 Nov 2020 00:11:35 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).                                                  | (b) (4), (b) (6)      | 07 Nov 2020 00:11:13 |
| Query 'PV Query: Please report if the subject had any prior history of anemia, or risk factors for developing anemia.' answered with 'No history of anemia reported. ' (Site from Safety).                                      | Danuel Hamlin (b) (4) | 06 Nov 2020 00:29:04 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Pending receipt of outside medical records. ' (Site from Safety). | Danuel Hamlin (b) (4) | 06 Nov 2020 00:28:50 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).                                                  | (b) (4), (b) (6)      | 30 Oct 2020 22:59:27 |
| User opened query 'PV Query: Please report if the subject had any prior history of anemia, or risk factors for developing anemia.' (Site from Safety).                                                                          | (b) (4), (b) (6)      | 30 Oct 2020 22:58:59 |

US3462255

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User entered '57 year old female with hypertension, type II diabetes, GERD, and history of gastric bypass surgery on 02OCT2020. Subject woke up 16OCT2020 with increased fatigue and malaise. Those symptoms had been ongoing for approximately one week prior, but suddenly worsened. Subject went to Emergency Department morning of 16OCT2020 at approximately 09:30 and was diagnosed with severe dehydration and anemia. Subject was treated with IV fluids and iron supplementation. Subject was admitted to monitor kidney function. Symptoms improved with treatments. Subject was discharged 17OCT2020 at approximately 12:00 with instructions to take over the counter iron supplementation.' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Oct 2020 00:23:29 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:31:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 21 Oct 2020 00:23:29 |

US3462255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:59

[Adverse event](#)

| Audit                                                                                                                                                                                       | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                         | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0. | Coder Import (b) (4)  | 21 Oct 2020 00:33:30 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                | (b) (4)               | 21 Oct 2020 00:33:30 |
| Data point term sent to Coder                                                                                                                                                               | Coder Import (b) (4)  | 21 Oct 2020 00:32:22 |
| User entered 'Anemia'                                                                                                                                                                       | System                | 21 Oct 2020 00:31:27 |
|                                                                                                                                                                                             | Danuel Hamlin (b) (4) |                      |
|                                                                                                                                                                                             |                       |                      |
|                                                                                                                                                                                             |                       |                      |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Was this a medically-attended AE?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |



US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '17 Oct 2020' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Start time \(00:00-23:59\)](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Ongoing?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

*If not Ongoing, end date (dd MMM yyyy)*

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[End time \(00:00-23:59\)](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |



US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Severity](#)

| Audit                                              | User                  | Time (GMT)           |
|----------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Is the adverse event serious?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:59

[Death](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Life threatening](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |



US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Admitted to ICU?](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Number of Days in ICU](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Persistent or significant disability or incapacity](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Congenital anomaly or birth defect](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Other medically important event](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:59

[Relationship to investigational product](#)

| Audit                                                                                  | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                | 21 Oct 2020 00:31:36 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 21 Oct 2020 00:31:36 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:36 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                | 21 Oct 2020 00:31:27 |
| User entered empty.                                                                    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Relationship to Study Procedure](#)

| Audit                                                                                  | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                | 21 Oct 2020 00:31:36 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 21 Oct 2020 00:31:36 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:36 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                | 21 Oct 2020 00:31:27 |
| User entered empty.                                                                    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Action taken with investigational product](#)

| Audit                                          | User                  | Time (GMT)           |
|------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |



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**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[None](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Concomitant Medication](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '1'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Concomitant Procedure](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Outcome](#)

| Audit                                                                  | User                  | Time (GMT)           |
|------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                    | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Narrative](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:41:12 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 21 Oct 2020 00:31:27 |

US3462255

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:31:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 21 Oct 2020 00:31:27 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 09:31:59**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:41:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:13:53 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Name of Medication](#)

| Audit                                                                                                                                                                                                               | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                 | (b) (4), (b) (6)                | 17 Nov 2020 22:52:02 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC:<br>DIURETICS, ATC: LOW-CEILING DIURETICS,<br>THIAZIDES, ATC: THIAZIDES, PLAIN,<br>PRODUCT: HYDROCHLOROTHIAZIDE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 20 Aug 2020 19:17:28 |
| 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) | 20 Aug 2020 19:17:28 |
| Data point term sent to Coder                                                                                                                                                                                       | System                          | 20 Aug 2020 19:16:08 |
| User entered 'hydrochlorathiazide'                                                                                                                                                                                  | (b) (4), (b) (6)                | 20 Aug 2020 19:15:19 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:52:02 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:15:19 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Indication](#)

| Audit                       | User             | Time (GMT)           |
|-----------------------------|------------------|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6) | 17 Nov 2020 22:52:02 |
| User entered 'hypertension' | (b) (4), (b) (6) | 20 Aug 2020 19:15:19 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 22:52:02 |
| User entered '12.5' | (b) (4), (b) (6) | 20 Aug 2020 19:15:19 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:52:02 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 20 Aug 2020 19:15:19 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 22:52:02 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:15:19 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 17 Nov 2020 22:52:02 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 20 Aug 2020 19:15:19 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 22:52:02 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:15:19 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 17 Nov 2020 22:52:02 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 20 Aug 2020 19:15:19 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 22:52:02 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:15:19 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

**Start date (dd MMM yyyy)**

| Audit                                                                                                                                                                                                                                                                                                            | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 17 Nov 2020 22:52:02 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.                                                                                                                                                                                              | System           | 21 Aug 2020 05:43:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System). | (b) (4), (b) (6) | 20 Aug 2020 19:15:28 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).                                                       | System           | 20 Aug 2020 19:15:19 |
| User entered 'un UNK 2000'                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6) | 20 Aug 2020 19:15:19 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 22:52:02 |
| User entered '0'    | (b) (4), (b) (6) | 20 Aug 2020 19:15:19 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:52:02 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:15:19 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 22:52:02 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:15:19 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Was this medication taken for solicited event?](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 17 Nov 2020 22:52:02 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 20 Aug 2020 19:15:39 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 20 Aug 2020 19:15:39 |
| User entered 'No (N)' reason for change: Data Entry Error                              | (b) (4), (b) (6) | 20 Aug 2020 19:15:39 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 20 Aug 2020 19:15:19 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 20 Aug 2020 19:15:19 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:15:19 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:15:19 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Aug 2020 19:15:19 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                               | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                 | (b) (4), (b) (6)                | 17 Nov 2020 22:52:44 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: OXICAMS, PRODUCT:<br>MELOXICAM - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 20 Aug 2020 19:18:18 |
| 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) | 20 Aug 2020 19:18:18 |
| Data point term sent to Coder                                                                                                                                                                                                                                       | System                          | 20 Aug 2020 19:17:10 |
| User entered 'meloxicam'                                                                                                                                                                                                                                            | (b) (4), (b) (6)                | 20 Aug 2020 19:16:40 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:52:44 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:16:40 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Indication](#)

| Audit                         | User             | Time (GMT)           |
|-------------------------------|------------------|----------------------|
| DataPoint Verified.           | (b) (4), (b) (6) | 17 Nov 2020 22:52:44 |
| User entered 'osteoarthritis' | (b) (4), (b) (6) | 20 Aug 2020 19:16:40 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose per administration](#)

| Audit                                                                                                                                                                                                     | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per CDM, per eCRF completion guidelines unknown dose should be recorded as UNK. Please update UNKNOWN to UNK, otherwise provide dose if known.' (Site from DM).<br>DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 11:15:28 |
|                                                                                                                                                                                                           | (b) (4), (b) (6)      | 17 Nov 2020 22:52:44 |
| User entered '15' reason for change: Data Entry Error                                                                                                                                                     | Danuel Hamlin (b) (4) | 06 Nov 2020 00:18:17 |
| Query 'Per CDM, per eCRF completion guidelines unknown dose should be recorded as UNK. Please update UNKNOWN to UNK, otherwise provide dose if known.' answered with 'Corrected' (Site from DM).          | Danuel Hamlin (b) (4) | 06 Nov 2020 00:17:43 |
| User entered 'UNK' reason for change: Data Entry Error                                                                                                                                                    | Danuel Hamlin (b) (4) | 06 Nov 2020 00:17:37 |
| User opened query 'Per CDM, per eCRF completion guidelines unknown dose should be recorded as UNK. Please update UNKNOWN to UNK, otherwise provide dose if known.' (Site from DM).                        | (b) (4), (b) (6)      | 09 Sep 2020 09:29:01 |
| User entered 'unknown'                                                                                                                                                                                    | (b) (4), (b) (6)      | 20 Aug 2020 19:16:40 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose unit](#)

| Audit                                                      | User                  | Time (GMT)           |
|------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                        | (b) (4), (b) (6)      | 17 Nov 2020 22:52:44 |
| User entered 'mg (mg)' reason for change: Data Entry Error | Danuel Hamlin (b) (4) | 06 Nov 2020 00:18:17 |
| User entered 'Other (OTHER)'                               | (b) (4), (b) (6)      | 20 Aug 2020 19:16:40 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

[If dose unit is Other, specify](#)

| Audit                                                  | User                  | Time (GMT)           |
|--------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)      | 17 Nov 2020 22:52:44 |
| User entered empty; reason for change Data Entry Error | Danuel Hamlin (b) (4) | 06 Nov 2020 00:18:17 |
| User entered 'unknown'                                 | (b) (4), (b) (6)      | 20 Aug 2020 19:16:40 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 17 Nov 2020 22:52:44 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 20 Aug 2020 19:16:40 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 22:52:44 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:16:40 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 17 Nov 2020 22:52:44 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 20 Aug 2020 19:16:40 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 22:52:44 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:16:40 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date \(dd MMM yyyy\)](#)

| Audit                                                                                                                                                                                                                                                                                                            | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 17 Nov 2020 22:52:44 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.                                                                                                                                                                                              | System           | 21 Aug 2020 05:43:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System). | (b) (4), (b) (6) | 20 Aug 2020 19:39:02 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).                                                       | System           | 20 Aug 2020 19:16:40 |
| User entered 'un UNK 2019'                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6) | 20 Aug 2020 19:16:40 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 22:52:44 |
| User entered '0'    | (b) (4), (b) (6) | 20 Aug 2020 19:16:40 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:52:44 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:16:40 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 22:52:44 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:16:40 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:52:44 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:16:40 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:16:40 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:16:40 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:16:40 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                   | User                  | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                     | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 06 Nov 2020 00:20:24 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                               | Coder Import (b) (4)  | 06 Nov 2020 00:20:24 |
| Data point term sent to Coder                                                                                                                                                                                           | System                | 06 Nov 2020 00:19:40 |
| Coding entries removed.                                                                                                                                                                                                 | Danuel Hamlin (b) (4) | 06 Nov 2020 00:19:13 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 20 Aug 2020 19:20:24 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                               | Coder Import (b) (4)  | 20 Aug 2020 19:20:24 |
| Data point term sent to Coder                                                                                                                                                                                           | System                | 20 Aug 2020 19:19:19 |
| User entered 'metformin'                                                                                                                                                                                                | (b) (4), (b) (6)      | 20 Aug 2020 19:18:43 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:18:43 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

[Indication](#)

| Audit                                                                  | User                  | Time (GMT)           |
|------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                    | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'Type II Diabetes' reason for change:<br>Data Entry Error | Danuel Hamlin (b) (4) | 06 Nov 2020 00:19:13 |
| User entered 'DMT2'                                                    | (b) (4), (b) (6)      | 20 Aug 2020 19:18:43 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose per administration](#)

| Audit                                                                                                                                                                                              | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Please consider recording these two dose separately instead of recording the both in the same entry. Update as appropriate.' (Site from DM).<br>DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 11:16:29 |
|                                                                                                                                                                                                    | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered '2500' reason for change: Data Entry Error                                                                                                                                            | Danuel Hamlin (b) (4) | 06 Nov 2020 00:20:33 |
| Query 'Per DM CLR: Please consider recording these two dose separately instead of recording the both in the same entry. Update as appropriate.' answered with 'Corrected' (Site from DM).          | Danuel Hamlin (b) (4) | 06 Nov 2020 00:19:10 |
| User entered '1000' reason for change: Data Entry Error                                                                                                                                            | Danuel Hamlin (b) (4) | 06 Nov 2020 00:18:57 |
| User opened query 'Per DM CLR: Please consider recording these two dose separately instead of recording the both in the same entry. Update as appropriate.' (Site from DM).                        | (b) (4), (b) (6)      | 12 Oct 2020 06:24:41 |
| User entered '1000 mg q am; 1500 mg qpm'                                                                                                                                                           | (b) (4), (b) (6)      | 20 Aug 2020 19:18:43 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 20 Aug 2020 19:18:43 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:18:43 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

[Frequency](#)

| Audit                                                                                                                                                                                                                      | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                        | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User opened query 'Per source, subject is taking Metformin twice daily (1000mg in the AM starting in 2017 and 1500mg in the PM starting in Feb2020). Please split these into 2 separate ConMed entries. ' (Site from CRA). | (b) (4), (b) (6)      | 17 Nov 2020 22:55:08 |
| User entered 'once daily (QD)' reason for change: Data Entry Error                                                                                                                                                         | Danuel Hamlin (b) (4) | 06 Nov 2020 00:20:33 |
| User entered 'twice daily (BID)'                                                                                                                                                                                           | (b) (4), (b) (6)      | 20 Aug 2020 19:18:43 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:18:43 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 20 Aug 2020 19:18:43 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:18:43 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

**Start date (dd MMM yyyy)**

| Audit                                                                                                                                                                                                                                                                                                            | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.                                                                                                                                                                                              | System           | 21 Aug 2020 05:43:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System). | (b) (4), (b) (6) | 20 Aug 2020 19:19:23 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).                                                       | System           | 20 Aug 2020 19:19:17 |
| User entered 'un Feb 2020' reason for change: Data Entry Error                                                                                                                                                                                                                                                   | (b) (4), (b) (6) | 20 Aug 2020 19:19:17 |
| User entered '20 Aug 2020'                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6) | 20 Aug 2020 19:18:43 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '0'    | (b) (4), (b) (6) | 20 Aug 2020 19:18:43 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:18:43 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:18:43 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:18:43 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Nov 2020 00:20:33 |
| User entered '2' | System | 20 Aug 2020 19:18:43 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:18:43 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Aug 2020 19:18:43 |

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:59

[Name of Medication](#)

| Audit                                                                                                                                                                                                                    | User                            | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                      | (b) (4), (b) (6)                | 17 Nov 2020 23:00:31 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: BETA<br>BLOCKING AGENTS, ATC: BETA BLOCKING<br>AGENTS, ATC: BETA BLOCKING AGENTS,<br>SELECTIVE, PRODUCT: METOPROLOL -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Nov 2020 11:13:32 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.                                                                                                               | Coder Import (b) (4)<br>(b) (4) | 06 Nov 2020 11:13:32 |
| Data point term sent to Coder                                                                                                                                                                                            | System                          | 06 Nov 2020 00:21:43 |
| Coding entries removed.                                                                                                                                                                                                  | Danuel Hamlin (b) (4)           | 06 Nov 2020 00:21:28 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: BETA<br>BLOCKING AGENTS, ATC: BETA BLOCKING<br>AGENTS, ATC: BETA BLOCKING AGENTS,<br>SELECTIVE, PRODUCT: METOPROLOL -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 20 Aug 2020 19:22:28 |
| 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) | 20 Aug 2020 19:22:28 |
| Data point term sent to Coder                                                                                                                                                                                            | System                          | 20 Aug 2020 19:21:27 |
| User entered 'metoprolol'                                                                                                                                                                                                | (b) (4), (b) (6)                | 20 Aug 2020 19:20:27 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:20:27 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

[Indication](#)

| Audit                                                                                                                                                                                                                                                                                                      | User                  | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Please update the indication to reflect the type of TACHYCARDIA (e.g., SINUS TACHYCARDIA, VENTRICULAR TACHYCARDIA, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.<br>' (Site from DM).                                       | (b) (4), (b) (6)      | 18 Nov 2020 11:17:48 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| Query 'Per DM CLR: Please update the indication to reflect the type of TACHYCARDIA (e.g., SINUS TACHYCARDIA, VENTRICULAR TACHYCARDIA, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.<br>' answered with 'Type of tachycardia not specified' (Site from DM). | Danuel Hamlin (b) (4) | 06 Nov 2020 00:21:32 |
| User entered 'Occasional TACHYCARDIA' reason for change: Data Entry Error                                                                                                                                                                                                                                  | Danuel Hamlin (b) (4) | 06 Nov 2020 00:21:28 |
| User opened query 'Per DM CLR: Please update the indication to reflect the type of TACHYCARDIA (e.g., SINUS TACHYCARDIA, VENTRICULAR TACHYCARDIA, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.<br>' (Site from DM).                                       | (b) (4), (b) (6)      | 21 Oct 2020 07:26:59 |
| User entered 'tachycardia'                                                                                                                                                                                                                                                                                 | (b) (4), (b) (6)      | 20 Aug 2020 19:20:27 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '25'   | (b) (4), (b) (6) | 20 Aug 2020 19:20:27 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 20 Aug 2020 19:20:27 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:20:27 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 20 Aug 2020 19:20:27 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:20:27 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 20 Aug 2020 19:20:27 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:20:27 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

**Start date (dd MMM yyyy)**

| Audit                                                                                                                                                                                                                                                                                                            | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.                                                                                                                                                                                              | System           | 21 Aug 2020 05:43:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System). | (b) (4), (b) (6) | 20 Aug 2020 19:20:37 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).                                                       | System           | 20 Aug 2020 19:20:27 |
| User entered 'un UNK 2000'                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6) | 20 Aug 2020 19:20:27 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '0'    | (b) (4), (b) (6) | 20 Aug 2020 19:20:27 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:20:27 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:20:27 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

[Was this medication taken for solicited event?](#)

| Audit                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 20 Aug 2020 19:20:40 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 20 Aug 2020 19:20:40 |
| User entered 'No (N)' reason for change: Data Entry Error                              | (b) (4), (b) (6) | 20 Aug 2020 19:20:40 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 20 Aug 2020 19:20:27 |
| User entered empty.                                                                    | (b) (4), (b) (6) | 20 Aug 2020 19:20:27 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:20:27 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:20:27 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Aug 2020 19:20:27 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                 | User                            | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                   | (b) (4), (b) (6)                | 17 Nov 2020 23:00:31 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 20 Aug 2020 19:23:31 |
| 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) | 20 Aug 2020 19:23:31 |
| Data point term sent to Coder                                                                                                                                                                                                                                         | System                          | 20 Aug 2020 19:22:28 |
| User entered 'omeprazole'                                                                                                                                                                                                                                             | (b) (4), (b) (6)                | 20 Aug 2020 19:21:35 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:21:35 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

[Indication](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'GERD' | (b) (4), (b) (6) | 20 Aug 2020 19:21:35 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '40'   | (b) (4), (b) (6) | 20 Aug 2020 19:21:35 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 20 Aug 2020 19:21:35 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:21:35 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 20 Aug 2020 19:21:35 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:21:35 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 20 Aug 2020 19:21:35 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:21:35 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                            | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.                                                                                                                                                                                              | System           | 21 Aug 2020 05:43:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System). | (b) (4), (b) (6) | 20 Aug 2020 19:21:41 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).                                                       | System           | 20 Aug 2020 19:21:35 |
| User entered 'un UNK 1995'                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6) | 20 Aug 2020 19:21:35 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '0'    | (b) (4), (b) (6) | 20 Aug 2020 19:21:35 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:21:35 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:21:35 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:21:35 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:21:35 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:21:35 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Aug 2020 19:21:35 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                        | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)                | 17 Nov 2020 23:00:31 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 21 Aug 2020 04:03:14 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                                                                                                                                         | Coder Import (b) (4)<br>(b) (4) | 21 Aug 2020 04:03:14 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                | System                          | 20 Aug 2020 19:23:32 |
| User entered 'aspirin'                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)                | 20 Aug 2020 19:22:50 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

[Prophylaxis](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:22:50 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

[Indication](#)

| Audit                       | User             | Time (GMT)           |
|-----------------------------|------------------|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'cardiac risk' | (b) (4), (b) (6) | 20 Aug 2020 19:22:50 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '81'   | (b) (4), (b) (6) | 20 Aug 2020 19:22:50 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 20 Aug 2020 19:22:50 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:22:50 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 20 Aug 2020 19:22:50 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:22:50 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 20 Aug 2020 19:22:50 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:22:50 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                            | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.                                                                                                                                                                                              | System           | 21 Aug 2020 05:43:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System). | (b) (4), (b) (6) | 20 Aug 2020 19:22:55 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).                                                       | System           | 20 Aug 2020 19:22:50 |
| User entered 'un UNK 1995'                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6) | 20 Aug 2020 19:22:50 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '0'    | (b) (4), (b) (6) | 20 Aug 2020 19:22:50 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:22:50 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:22:50 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:22:50 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:22:50 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:22:50 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Aug 2020 19:22:50 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                              | User                            | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                | (b) (4), (b) (6)                | 17 Nov 2020 23:00:31 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: LIPID<br>MODIFYING AGENTS, ATC: LIPID MODIFYING<br>AGENTS, PLAIN, ATC: HMG COA REDUCTASE<br>INHIBITORS, PRODUCT: ATORVASTATIN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 20 Aug 2020 19:25:25 |
| 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) | 20 Aug 2020 19:25:25 |
| Data point term sent to Coder                                                                                                                                                                                                      | System                          | 20 Aug 2020 19:24:32 |
| User entered 'atorvastatin'                                                                                                                                                                                                        | (b) (4), (b) (6)                | 20 Aug 2020 19:24:12 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:24:12 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

[Indication](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| DataPoint Verified.                 | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'hypercholesterolemia' | (b) (4), (b) (6) | 20 Aug 2020 19:24:12 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '10'   | (b) (4), (b) (6) | 20 Aug 2020 19:24:12 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 20 Aug 2020 19:24:12 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:24:12 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 20 Aug 2020 19:24:12 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:24:12 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 20 Aug 2020 19:24:12 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:24:12 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                            | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.                                                                                                                                                                                              | System           | 21 Aug 2020 05:43:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System). | (b) (4), (b) (6) | 20 Aug 2020 19:24:26 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).                                                       | System           | 20 Aug 2020 19:24:12 |
| User entered 'un UNK 2010'                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6) | 20 Aug 2020 19:24:12 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '0'    | (b) (4), (b) (6) | 20 Aug 2020 19:24:12 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:24:12 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:24:12 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:24:12 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:24:12 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:24:12 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Aug 2020 19:24:12 |

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:59

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                             | User                            | Time (GMT)                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------|
| DataPoint Verified.                                                                                                                                                                                                                               | (b) (4), (b) (6)                | 17 Nov 2020 23:00:31                         |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE<br>RELAXANTS, ATC: MUSCLE RELAXANTS,<br>CENTRALLY ACTING AGENTS, ATC: OTHER<br>CENTRALLY ACTING AGENTS, PRODUCT:<br>CYCLOBENZAPRINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Nov 2020 00:23:29                         |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.                                                                                                                                   | Coder Import (b) (4)<br>(b) (4) | 06 Nov 2020 00:23:29                         |
| Data point term sent to Coder<br>Coding entries removed.                                                                                                                                                                                          | System<br>Danuel Hamlin (b) (4) | 06 Nov 2020 00:22:44<br>06 Nov 2020 00:22:06 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE<br>RELAXANTS, ATC: MUSCLE RELAXANTS,<br>CENTRALLY ACTING AGENTS, ATC: OTHER<br>CENTRALLY ACTING AGENTS, PRODUCT:<br>CYCLOBENZAPRINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 20 Aug 2020 19:26:26                         |
| 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) | 20 Aug 2020 19:26:26                         |
| Data point term sent to Coder<br>User entered 'cyclobenzaprine'                                                                                                                                                                                   | System<br>(b) (4), (b) (6)      | 20 Aug 2020 19:25:36<br>20 Aug 2020 19:25:33 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:25:33 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

[Indication](#)

| Audit                                                                                                                                                                                                                                                                               | User                  | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 11:18:31 |
|                                                                                                                                                                                                                                                                                     | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'Corrected' (Site from DM).       | Danuel Hamlin (b) (4) | 06 Nov 2020 00:22:10 |
| User entered 'Lower BACK PAIN' reason for change: Data Entry Error                                                                                                                                                                                                                  | Danuel Hamlin (b) (4) | 06 Nov 2020 00:22:06 |
| User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).                     | (b) (4), (b) (6)      | 12 Oct 2020 11:44:00 |
| User entered 'back pain'                                                                                                                                                                                                                                                            | (b) (4), (b) (6)      | 20 Aug 2020 19:25:33 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '10'   | (b) (4), (b) (6) | 20 Aug 2020 19:25:33 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 20 Aug 2020 19:25:33 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:25:33 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 20 Aug 2020 19:25:33 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:25:33 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 20 Aug 2020 19:25:33 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:25:33 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '29 Jul 2020' | (b) (4), (b) (6) | 20 Aug 2020 19:25:33 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '0'    | (b) (4), (b) (6) | 20 Aug 2020 19:25:33 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:25:33 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:25:33 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

[Was this medication taken for solicited event?](#)

| Audit                                                                                                                                                                                                                                            | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' (Site from DM). DataPoint Verified. | (b) (4), (b) (6)      | 18 Nov 2020 11:18:44 |
| Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' answered with 'Corrected' (Site from DM).       | Danuel Hamlin (b) (4) | 06 Nov 2020 00:22:24 |
| User entered 'No (N)' reason for change: Data Entry Error                                                                                                                                                                                        | Danuel Hamlin (b) (4) | 06 Nov 2020 00:22:19 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify.' (Site from DM).                     | (b) (4), (b) (6)      | 12 Oct 2020 11:44:19 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                           | (b) (4), (b) (6)      | 20 Aug 2020 19:25:33 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:25:33 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:25:33 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 19:25:33 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

[Name of Medication](#)

| Audit                                                                                                                                                                | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                  | (b) (4), (b) (6)                | 17 Nov 2020 23:00:31 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 20 Aug 2020 19:35:30 |
| 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) | 20 Aug 2020 19:35:30 |
| Data point term sent to Coder                                                                                                                                        | System                          | 20 Aug 2020 19:35:03 |
| User entered 'duloxetine'                                                                                                                                            | (b) (4), (b) (6)                | 20 Aug 2020 19:34:22 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:34:22 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

[Indication](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'anxiety' | (b) (4), (b) (6) | 20 Aug 2020 19:34:22 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '60'   | (b) (4), (b) (6) | 20 Aug 2020 19:34:22 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 20 Aug 2020 19:34:22 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:34:22 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 20 Aug 2020 19:34:22 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:34:22 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 20 Aug 2020 19:34:22 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:34:22 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                            | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.                                                                                                                                                                                              | System           | 21 Aug 2020 05:43:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System). | (b) (4), (b) (6) | 20 Aug 2020 19:34:28 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).                                                       | System           | 20 Aug 2020 19:34:22 |
| User entered 'un UNK 2000'                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6) | 20 Aug 2020 19:34:22 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '0'    | (b) (4), (b) (6) | 20 Aug 2020 19:34:22 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:34:22 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:34:22 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:34:22 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:34:22 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:34:22 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Aug 2020 19:34:22 |

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:59

[Name of Medication](#)

| Audit                                                                                                                                                                                                   | User                             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                     | (b) (4), (b) (6)                 | 17 Nov 2020 23:00:31 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 06 Nov 2020 10:14:32 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                                                    | Coder Import (b) (4)<br>(b) (4)  | 06 Nov 2020 10:14:32 |
| Data point term sent to Coder                                                                                                                                                                           | System                           | 06 Nov 2020 00:27:47 |
| Coding entries removed.                                                                                                                                                                                 | Danuel Hamlin (b) (4)<br>(b) (4) | 06 Nov 2020 00:26:48 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 21 Aug 2020 05:16:10 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                                                    | Coder Import (b) (4)<br>(b) (4)  | 21 Aug 2020 05:16:10 |
| Data point term sent to Coder                                                                                                                                                                           | System                           | 20 Aug 2020 19:37:06 |
| User entered 'gabapentin'                                                                                                                                                                               | (b) (4), (b) (6)<br>(b) (4)      | 20 Aug 2020 19:36:11 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:36:11 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

[Indication](#)

| Audit                                                                                                                                                                                                                                                                                        | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS (rheumatoid, gout, osteoarthritis). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.<br>' (Site from DM).                                                | (b) (4), (b) (6)      | 18 Nov 2020 11:18:57 |
| DataPoint Verified.                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| Query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS (rheumatoid, gout, osteoarthritis). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.<br>' answered with 'Specific type of arthritis is unknown.<br>' (Site from DM). | Danuel Hamlin (b) (4) | 06 Nov 2020 00:27:22 |
| User entered 'BILATERAL KNEE ARTHRITIS' reason for change: Data Entry Error                                                                                                                                                                                                                  | Danuel Hamlin (b) (4) | 06 Nov 2020 00:26:48 |
| User opened query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS (rheumatoid, gout, osteoarthritis). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.<br>' (Site from DM).                                                | (b) (4), (b) (6)      | 21 Oct 2020 07:25:31 |
| User entered 'arthritis knees'                                                                                                                                                                                                                                                               | (b) (4), (b) (6)      | 20 Aug 2020 19:36:11 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '300'  | (b) (4), (b) (6) | 20 Aug 2020 19:36:11 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 20 Aug 2020 19:36:11 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:36:11 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

[Frequency](#)

| Audit                                  | User             | Time (GMT)           |
|----------------------------------------|------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'three times daily (TID)' | (b) (4), (b) (6) | 20 Aug 2020 19:36:11 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:36:11 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 20 Aug 2020 19:36:11 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:36:11 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                            | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.                                                                                                                                                                                              | System           | 21 Aug 2020 05:43:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System). | (b) (4), (b) (6) | 20 Aug 2020 19:37:18 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).                                                       | System           | 20 Aug 2020 19:36:11 |
| User entered 'un May 2020'                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6) | 20 Aug 2020 19:36:11 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '0'    | (b) (4), (b) (6) | 20 Aug 2020 19:36:11 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:36:11 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:36:11 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:36:11 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 20 Aug 2020 19:36:11 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:36:11 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Aug 2020 19:36:11 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                      | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                        | (b) (4), (b) (6)                | 17 Nov 2020 23:00:31 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 06 Nov 2020 00:18:24 |
| 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) | 06 Nov 2020 00:18:24 |
| Data point term sent to Coder                                                                                                                                                                                              | System                          | 06 Nov 2020 00:17:39 |
| Coding entries removed.                                                                                                                                                                                                    | Danuel Hamlin (b) (4)           | 06 Nov 2020 00:17:12 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 21 Aug 2020 05:14:18 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                                                                       | Coder Import (b) (4)<br>(b) (4) | 21 Aug 2020 05:14:18 |
| Data point term sent to Coder                                                                                                                                                                                              | System                          | 20 Aug 2020 19:37:07 |
| User entered 'glipizide'                                                                                                                                                                                                   | (b) (4), (b) (6)                | 20 Aug 2020 19:37:05 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:37:05 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

[Indication](#)

| Audit                                                                  | User                  | Time (GMT)           |
|------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                    | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'Type II Diabetes' reason for change:<br>Data Entry Error | Danuel Hamlin (b) (4) | 06 Nov 2020 00:17:12 |
| User entered 'T2DM'                                                    | (b) (4), (b) (6)      | 20 Aug 2020 19:37:05 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '5'    | (b) (4), (b) (6) | 20 Aug 2020 19:37:05 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 20 Aug 2020 19:37:05 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:37:05 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

[Frequency](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'twice daily (BID)' | (b) (4), (b) (6) | 20 Aug 2020 19:37:05 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:37:05 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 20 Aug 2020 19:37:05 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:37:05 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                            | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.                                                                                                                                                                                              | System           | 21 Aug 2020 05:43:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System). | (b) (4), (b) (6) | 20 Aug 2020 19:37:10 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).                                                       | System           | 20 Aug 2020 19:37:05 |
| User entered 'un Jan 2020'                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6) | 20 Aug 2020 19:37:05 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '0'    | (b) (4), (b) (6) | 20 Aug 2020 19:37:05 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:37:05 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:37:05 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:37:05 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 20 Aug 2020 19:37:05 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:37:05 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Aug 2020 19:37:05 |

US3462255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:59

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                    | User                            | Time (GMT)                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------|
| DataPoint Verified.                                                                                                                                                                                                                                      | (b) (4), (b) (6)                | 17 Nov 2020 23:00:31                         |
| User coded data point as ATC: SENSORY<br>ORGANS, ATC: OPHTHALMOLOGICALS, ATC:<br>DECONGESTANTS AND ANTIALLERGICS,<br>ATC: OTHER ANTIALLERGICS, PRODUCT:<br>CETIRIZINE HYDROCHLORIDE,<br>PRODUCTSYNONYM: ALLERTEC - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 10 Nov 2020 19:37:38                         |
| 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) | 10 Nov 2020 19:37:38                         |
| Data point term sent to Coder<br>Coding entries removed.                                                                                                                                                                                                 | System<br>Danuel Hamlin (b) (4) | 06 Nov 2020 00:17:37<br>06 Nov 2020 00:16:44 |
| User coded data point as ATC: SENSORY<br>ORGANS, ATC: OPHTHALMOLOGICALS, ATC:<br>DECONGESTANTS AND ANTIALLERGICS,<br>ATC: OTHER ANTIALLERGICS, PRODUCT:<br>CETIRIZINE HYDROCHLORIDE,<br>PRODUCTSYNONYM: ALLERTEC - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 20 Aug 2020 22:05:27                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.                                                                                                                                               | Coder Import (b) (4)<br>(b) (4) | 20 Aug 2020 22:05:27                         |
| Data point term sent to Coder<br>User entered 'allertec'                                                                                                                                                                                                 | System<br>(b) (4), (b) (6)      | 20 Aug 2020 19:39:10<br>20 Aug 2020 19:38:16 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:38:16 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

[Indication](#)

| Audit                                                                                                       | User                  | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                         | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'Seasonal Allergic Rhinitis / Perennial Allergic Rhinitis' reason for change: Data Entry Error | Danuel Hamlin (b) (4) | 06 Nov 2020 00:16:44 |
| User entered 'SAR/PAR'                                                                                      | (b) (4), (b) (6)      | 20 Aug 2020 19:38:16 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose per administration](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered '10'   | (b) (4), (b) (6) | 20 Aug 2020 19:38:16 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 20 Aug 2020 19:38:16 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:38:16 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

[Frequency](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 20 Aug 2020 19:38:16 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:38:16 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 20 Aug 2020 19:38:16 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:38:16 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                            | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.                                                                                                                                                                                              | System           | 21 Aug 2020 05:43:24 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Confirmed start date; currently taking medication' (Site from System). | (b) (4), (b) (6) | 20 Aug 2020 19:38:26 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).                                                       | System           | 20 Aug 2020 19:38:16 |
| User entered 'un UNK 2015'                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6) | 20 Aug 2020 19:38:16 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit                                                                                                                             | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                               | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System). | System           | 20 Aug 2020 19:38:29 |
| User entered '0' reason for change: Data Entry Error                                                                              | (b) (4), (b) (6) | 20 Aug 2020 19:38:29 |
| User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System). | System           | 20 Aug 2020 19:38:16 |
| User entered '1'                                                                                                                  | (b) (4), (b) (6) | 20 Aug 2020 19:38:16 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

[Ongoing?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Aug 2020 19:38:16 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered empty. | (b) (4), (b) (6) | 20 Aug 2020 19:38:16 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 20 Aug 2020 19:38:16 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:38:16 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 19:38:16 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Aug 2020 19:38:16 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Name of Medication](#)

| Audit                                                                                                                                                                                                         | User                                        | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                           | (b) (4), (b) (6)                            | 17 Nov 2020 23:00:31 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)             | 21 Oct 2020 00:31:27 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                     | Coder Import (b) (4)<br>(b) (4)             | 21 Oct 2020 00:31:27 |
| Data point term sent to Coder                                                                                                                                                                                 | System                                      | 21 Oct 2020 00:30:19 |
| User entered 'Iron Supplement'                                                                                                                                                                                | Danuel Hamlin (b) (4)<br>(b) (4)<br>(b) (4) | 21 Oct 2020 00:29:36 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Prophylaxis](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:29:36 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Indication](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'Anemia' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:29:36 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose per administration](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered '325'  | Danuel Hamlin (b) (4) | 21 Oct 2020 00:29:36 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose unit](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'mg (mg)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:29:36 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

[If dose unit is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:29:36 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Frequency](#)

| Audit                                | User                  | Time (GMT)           |
|--------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'every other day (QOD)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:29:36 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

[If frequency is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:29:36 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'Oral (ORAL)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:29:36 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

If route of administration is Other, specify

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:29:36 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered '16 Oct 2020' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:29:36 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered '0'    | Danuel Hamlin (b) (4) | 21 Oct 2020 00:29:36 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Ongoing?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:29:36 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:29:36 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Was this medication taken for solicited event?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:29:36 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Oct 2020 00:29:36 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 21 Oct 2020 00:29:36 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Oct 2020 00:29:36 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                          | User                                        | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                            | (b) (4), (b) (6)                            | 17 Nov 2020 23:00:31 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: VICODIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)             | 06 Nov 2020 05:36:29 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                                                                                           | Coder Import (b) (4)<br>(b) (4)             | 06 Nov 2020 05:36:29 |
| Data point term sent to Coder                                                                                                                                                                                                                  | System                                      | 06 Nov 2020 00:59:06 |
| User entered 'Vicodin (325/5 mg)'                                                                                                                                                                                                              | Danuel Hamlin (b) (4)<br>(b) (4)<br>(b) (4) | 06 Nov 2020 00:58:07 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Prophylaxis](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:58:07 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Indication](#)

| Audit                                           | User                  | Time (GMT)           |
|-------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                             | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'Post Gastric Bypass Surgery Pain' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:58:07 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose per administration](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered '1'    | Danuel Hamlin (b) (4) | 06 Nov 2020 00:58:07 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Dose unit](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'tablet (TABLET)' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:58:07 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

[If dose unit is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 00:58:07 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Frequency](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'as needed (PRN)' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:58:07 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

[If frequency is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 00:58:07 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'Oral (ORAL)' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:58:07 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

If route of administration is Other, specify

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered empty. | Danuel Hamlin (b) (4) | 06 Nov 2020 00:58:07 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered '02 Oct 2020' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:58:07 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Start date completely unknown](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered '0'    | Danuel Hamlin (b) (4) | 06 Nov 2020 00:58:07 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Ongoing?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:58:07 |



US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered '03 Oct 2020' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:58:07 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Was this medication taken for solicited event?](#)

| Audit                 | User                  | Time (GMT)           |
|-----------------------|-----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)      | 17 Nov 2020 23:00:31 |
| User entered 'No (N)' | Danuel Hamlin (b) (4) | 06 Nov 2020 00:58:07 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:58:07 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:58:07 |

US3462255

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:31:59**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:58:07 |

US3462255

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 09:31:59**

[Were any concomitant procedures performed?](#)

| Audit                  | User                  | Time (GMT)           |
|------------------------|-----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)      | 17 Nov 2020 22:43:39 |
| User entered 'Yes (Y)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:25:44 |

US3462255

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)      | 17 Nov 2020 22:44:13 |
| User entered '02 Oct 2020' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:26:15 |

US3462255

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Procedure/Surgery](#)

| Audit                                 | User                  | Time (GMT)           |
|---------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                   | (b) (4), (b) (6)      | 17 Nov 2020 22:44:13 |
| User entered 'Gastric Bypass Surgery' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:26:15 |



US3462255

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:31:59**

[Indication](#)

| Audit                               | User                  | Time (GMT)           |
|-------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                 | (b) (4), (b) (6)      | 17 Nov 2020 22:44:13 |
| User entered 'Medical History (MH)' | Danuel Hamlin (b) (4) | 21 Oct 2020 00:26:15 |

US3462255

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:31:59**

[If indication is Other, specify](#)

| Audit               | User                  | Time (GMT)           |
|---------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)      | 17 Nov 2020 22:44:13 |
| User entered empty. | Danuel Hamlin (b) (4) | 21 Oct 2020 00:26:15 |

US3462255

**Folder: SAE USA-US093-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:31:59**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered<br>'USA-US093-2020-MRNA-1273-P301000008' | System           | 21 Oct 2020 21:06:01 |

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:59

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'Yes (Y)' | System           | 21 Oct 2020 21:06:01 |

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:59

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'No (N)' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'No (N)' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'Yes (Y)' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'No (N)' | System           | 21 Oct 2020 21:06:01 |



US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'No (N)' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'No (N)' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder: SAE USA-US093-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:31:59**

[Investigator's First Name](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'Edward' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder: SAE USA-US093-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:31:59**

[Investigator's Last Name](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'Kerwin' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Oct 2020 21:07:44 |
| User entered 'US'    | System           | 21 Oct 2020 21:07:34 |

US3462255

**Folder: SAE USA-US093-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:31:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 07 Nov 2020 00:07:15 |
| User entered '1' | System | 21 Oct 2020 21:07:34 |

US3462255

**Folder: SAE USA-US093-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:31:59**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered<br>'USA-US093-2020-MRNA-1273-P301000008' | System           | 21 Oct 2020 21:06:01 |

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:59

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'Yes (Y)' | System           | 21 Oct 2020 21:06:01 |



US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:59

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'No (N)' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'No (N)' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'Yes (Y)' | System           | 21 Oct 2020 21:06:01 |

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:59

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'No (N)' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'No (N)' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'No (N)' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder: SAE USA-US093-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:31:59**

[Investigator's First Name](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'Edward' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Investigator's Last Name](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'Kerwin' | System           | 21 Oct 2020 21:06:01 |



US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Oct 2020 21:07:44 |
| User entered 'US'    | System           | 21 Oct 2020 21:07:34 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 07 Nov 2020 00:07:15 |
| User entered '1' | System | 21 Oct 2020 21:07:34 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form (1)

**Generated On:** 26 Nov 2020 09:31:59

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| User entered '21/Oct/2020 21:07' | System           | 21 Oct 2020 21:07:34 |

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:31:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Oct 2020 21:07:44 |
| User entered '1'     | (b) (4), (b) (6) | 21 Oct 2020 21:07:34 |

US3462255

**Folder: SAE USA-US093-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:31:59**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered<br>'USA-US093-2020-MRNA-1273-P301000008' | System           | 21 Oct 2020 21:06:01 |

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:59

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'Yes (Y)' | System           | 21 Oct 2020 21:06:01 |

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:59

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'No (N)' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'No (N)' | System           | 21 Oct 2020 21:06:01 |



US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'Yes (Y)' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'No (N)' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'No (N)' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'No (N)' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder: SAE USA-US093-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:31:59**

[Investigator's First Name](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'Edward' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Investigator's Last Name](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 21 Oct 2020 21:07:14 |
| User entered 'Kerwin' | System           | 21 Oct 2020 21:06:01 |

US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:31:59

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Oct 2020 21:07:44 |
| User entered 'US'    | System           | 21 Oct 2020 21:07:34 |

US3462255

**Folder: SAE USA-US093-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:31:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 07 Nov 2020 00:07:15 |
| User entered '1' | System | 21 Oct 2020 21:07:34 |



US3462255

**Folder:** SAE USA-US093-2020-MRNA-1273-P301000008

**Form:** Safety Report Form (2)

**Generated On:** 26 Nov 2020 09:31:59

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| User entered '06/Nov/2020 19:07' | System           | 07 Nov 2020 00:07:15 |

US3462255

Folder: SAE USA-US093-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:31:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Nov 2020 22:15:08 |
| User entered '1'    | (b) (4), (b) (6) | 07 Nov 2020 00:07:15 |