

US3532002 (Prod: Children's Healthcare of Atlanta)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:34:14

All time stamps listed in this document are displayed in GMT

US3532002

**Form: Participant Creation**

**Generated On: 26 Nov 2020 09:34:14**

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[Participant ID](#)

US3532002

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

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US3532002

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:34:14

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 11 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 09:34:14

|                                           |                                                                                                                                                                            |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy)                  | (b) (6) 1956                                                                                                                                                               |
| Age                                       | 63                                                                                                                                                                         |
| Age Units                                 | YEARS                                                                                                                                                                      |
| Age (Derived)                             | 64                                                                                                                                                                         |
| Sex                                       | Female <input type="radio"/><br>Male <input checked="" 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 09:34:14

|                                                 |                                              |
|-------------------------------------------------|----------------------------------------------|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 11 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 09:34:14

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:34:14

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:14

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | HYPERTENSION                                                     |
| Start date (dd MMM yyyy)                          | UN UNK 1990                                                      |
| 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 1990                                                         |
| Start Year (derived)                              | 1990                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:14

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | TYPE 2 DIABETES                                                  |
| Start date (dd MMM yyyy)                          | UN UNK 2012                                                      |
| 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 2012                                                         |
| Start Year (derived)                              | 2012                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:14

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | BILATERAL GLAUCOMA                                               |
| Start date (dd MMM yyyy)                          | UN UNK 1977                                                      |
| 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 1977                                                         |
| Start Year (derived)                              | 1977                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:14

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | ELEVATED CHOLESTEROL                                             |
| Start date (dd MMM yyyy)                          | UN UNK 1990                                                      |
| 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 1990                                                         |
| Start Year (derived)                              | 1990                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:14

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:14

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | BACK SURGERY LUMBAR<br>LAMINECTOMY                               |
| Start date (dd MMM yyyy)                          | UN DEC 2019                                                      |
| 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 DEC 2019                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | DEC 2019                                                         |
| Start Year (derived)                              | 2019                                                             |
| Stop Month and Year (derived)                     | DEC 2019                                                         |
| Stop Year (derived)                               | 2019                                                             |

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:14

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | RIGHT ROTATOR CUFF TEAR                                          |
| Start date (dd MMM yyyy)                          | UN UNK 2004                                                      |
| 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 2005                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2004                                                         |
| Start Year (derived)                              | 2004                                                             |
| Stop Month and Year (derived)                     | JAN 2005                                                         |
| Stop Year (derived)                               | 2005                                                             |

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:14

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | RIGHT ROTATOR CUFF REPAIR                                        |
| Start date (dd MMM yyyy)                          | UN UNK 2005                                                      |
| 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 2005                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2005                                                         |
| Start Year (derived)                              | 2005                                                             |
| Stop Month and Year (derived)                     | JAN 2005                                                         |
| Stop Year (derived)                               | 2005                                                             |

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Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:14

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | RIGHT KNEE SCOPE                                                 |
| Start date (dd MMM yyyy)                          | UN UNK 1984                                                      |
| 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 1984                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 1984                                                         |
| Start Year (derived)                              | 1984                                                             |
| Stop Month and Year (derived)                     | JAN 1984                                                         |
| Stop Year (derived)                               | 1984                                                             |



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Form: Medical History (10)

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|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | RIGHT BROKEN FEMUR                                               |
| Start date (dd MMM yyyy)                          | UN UNK 1976                                                      |
| 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) |                                                                  |
| Stop date completely unknown                      | True                                                             |
| Start Month and Year (derived)                    | JAN 1976                                                         |
| Start Year (derived)                              | 1976                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:14

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | RIGHT FEMUR LENGTHENING SURGERY                                  |
| Start date (dd MMM yyyy)                          | UN UNK 1997                                                      |
| 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 1997                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 1997                                                         |
| Start Year (derived)                              | 1997                                                             |
| Stop Month and Year (derived)                     | JAN 1997                                                         |
| Stop Year (derived)                               | 1997                                                             |

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:14

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | BILATERAL CATARACTS                                              |
| Start date (dd MMM yyyy)                          | UN UNK 2018                                                      |
| 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 SEP 2018                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2018                                                         |
| Start Year (derived)                              | 2018                                                             |
| Stop Month and Year (derived)                     | SEP 2018                                                         |
| Stop Year (derived)                               | 2018                                                             |

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:34:14

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | BILATERAL CATARACT SURGERIES                                     |
| Start date (dd MMM yyyy)                          | UN SEP 2018                                                      |
| 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 SEP 2018                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | SEP 2018                                                         |
| Start Year (derived)                              | 2018                                                             |
| Stop Month and Year (derived)                     | SEP 2018                                                         |
| Stop Year (derived)                               | 2018                                                             |

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:34:14

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

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:34:14

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

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Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:34:14

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | TORN CARTILAGE IN RIGHT KNEE                                     |
| Start date (dd MMM yyyy)                          |                                                                  |
| Start date completely unknown                     | True                                                             |
| 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 1984                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    |                                                                  |
| Start Year (derived)                              |                                                                  |
| Stop Month and Year (derived)                     | JAN 1984                                                         |
| Stop Year (derived)                               | 1984                                                             |

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Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:34:14

|                                                   |                              |
|---------------------------------------------------|------------------------------|
| Condition                                         |                              |
| Start date (dd MMM yyyy)                          |                              |
| Start date completely unknown                     |                              |
| Condition ongoing at study entry                  | Yes <input type="checkbox"/> |
|                                                   | No <input type="checkbox"/>  |
| If No, please specify the stop date (dd MMM yyyy) |                              |
| Stop date completely unknown                      |                              |
| Start Month and Year (derived)                    |                              |
| Start Year (derived)                              |                              |
| Stop Month and Year (derived)                     |                              |
| Stop Year (derived)                               |                              |



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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:14

|                                           |                                      |
|-------------------------------------------|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|                                           | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 11 AUG 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 15:11 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 11 AUG 2020 15:11                    |
| Height ( <i>xxx.x</i> )                   | 174 cm                               |
| Weight ( <i>xxx.x</i> )                   | 85.5 kg                              |
| BMI ( <i>xxx.x</i> )                      | 28.24019 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

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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: Risk of Exposure

Generated On: 26 Nov 2020 09:34:14

**Occupational Risk**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

**Warehouse shipping and fulfillment centers** and jobs (e.g., Amazon facilities) Yes ☐ No ☒

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

**Other** Yes ☒ No ☐

**Specify**

ENGINEER-PERFORMS SITE  
INSPECTIONS 3X/WEEK

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

**No Risk Identified** False

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

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

v6.020 DTW (1102)

26 of 2036

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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 09:34:14

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 11 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 09:34:14

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 143706

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 09:34:14

|        |               |
|--------|---------------|
| 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 09:34:14

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 11 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 15:11 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 11 AUG 2020 15:11                                                                                      |
| Temperature (xxx.x)                 | 98.9 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 80 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 12 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 139 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 89 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 11 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 17:51 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 11 AUG 2020 17:51                                                                                      |
| Temperature (xxx.x)                 | 98.4 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 71 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 12 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 165 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 95 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

US3532002

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

US3532002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:14

|                                                                                                              |                                                                    |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| 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)                                                                   | 11 AUG 2020                                                        |
| What was the treatment time? (00:00-23:59)                                                                   | 17:21 (24 HR)                                                      |
| Treatment Date and Time (derived)                                                                            | 11 AUG 2020 17:21                                                  |
| 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                                                      |

US3532002

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:14

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 11 AUG 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 16:49 (24 HR)                        |
| Collection date and time (derived)     | 11 AUG 2020 16:49                    |

US3532002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:34:14

|                                        |                           |                                          |                                    |
|----------------------------------------|---------------------------|------------------------------------------|------------------------------------|
| Collection date ( <i>dd MMM yyyy</i> ) |                           |                                          | 11 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                       | 16:35                                    | 11 AUG 2020 16:35                  |
| Nasopharyngeal Swab 2                  | No                        |                                          |                                    |

US3532002

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:34:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 18:17

PC Open Date & Time

11 AUG 2020 17:41

PC Close Date & Time

11 AUG 2020 20:11

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**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

97.6 °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 11 AUG 2020 21:29

PC Open Date & Time 11 AUG 2020 21:06

PC Close Date & Time 12 AUG 2020 11:59



US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:34:14

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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

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

12 AUG 2020 12:18

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 16:35

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**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

98.0 °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

14 AUG 2020 18:21

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:34:14

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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

98.1 °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

15 AUG 2020 18:10

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**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

98.1 °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 AUG 2020 19:41

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:34:14

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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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 17:32

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**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

11 AUG 2020 18:18

PC Open Date & Time

11 AUG 2020 17:41

PC Close Date & Time

11 AUG 2020 20:11

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

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

2

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 21:32

PC Open Date & Time

11 AUG 2020 21:06

PC Close Date & Time

12 AUG 2020 11:59



US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:34:14

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

30

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

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

12 AUG 2020 12:20

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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

25

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

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

13 AUG 2020 16:36

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**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

14 AUG 2020 18:22

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**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

15 AUG 2020 18:11

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**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

16 AUG 2020 19:42

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**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

17 AUG 2020 17:33

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**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 ☐

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 11 AUG 2020 18:19 |
| PC Open Date & Time  | 11 AUG 2020 17:41 |
| PC Close Date & Time | 11 AUG 2020 20:11 |



US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**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 ☐

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 11 AUG 2020 21:33 |
| PC Open Date & Time  | 11 AUG 2020 21:06 |
| PC Close Date & Time | 12 AUG 2020 11:59 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

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 ☒

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 12 AUG 2020 12:22 |
| PC Open Date & Time          | 12 AUG 2020 12:00 |
| PC Close Date & Time         | 13 AUG 2020 11:59 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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 ☒

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 13 AUG 2020 16:37 |
| PC Open Date & Time          | 13 AUG 2020 12:00 |
| PC Close Date & Time         | 14 AUG 2020 11:59 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

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 ☒

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 14 AUG 2020 18:23 |
| PC Open Date & Time          | 14 AUG 2020 12:00 |
| PC Close Date & Time         | 15 AUG 2020 11:59 |



US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

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 ☒

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 15 AUG 2020 18:12 |
| PC Open Date & Time          | 15 AUG 2020 12:00 |
| PC Close Date & Time         | 16 AUG 2020 11:59 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

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 ☒

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 16 AUG 2020 19:42 |
| PC Open Date & Time          | 16 AUG 2020 12:00 |
| PC Close Date & Time         | 17 AUG 2020 11:59 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

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 ☒

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 17 AUG 2020 17:33 |
| PC Open Date & Time          | 17 AUG 2020 12:00 |
| PC Close Date & Time         | 18 AUG 2020 11:59 |

US3532002

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3532002

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3532002

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3532002

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3532002

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:14

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 8 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                                  |

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:14

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| 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)    | 8 SEP 2020                                |
| Time of assessment (00:00-23:59)    | 07:40 (24 HR)                             |
| Vital Signs Date and Time (derived) | 8 SEP 2020 07:40                          |
| Temperature (xxx.x)                 | 98.5 F                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |                                           |
| Pulse (xxx)                         | 64 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 16 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 114 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 75 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

|                                     |                                            |
|-------------------------------------|--------------------------------------------|
| 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)    | 8 SEP 2020                                 |
| Time of assessment (00:00-23:59)    | 09:12 (24 HR)                              |
| Vital Signs Date and Time (derived) | 8 SEP 2020 09:12                           |
| Temperature (xxx.x)                 | 97.2 F                                     |
| Route of measurement                | Oral <input checked="" type="radio"/>      |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input type="radio"/>                |
| If Other, specify                   |                                            |
| Pulse (xxx)                         | 61 beats/min                               |
| Pulse units                         | BPM                                        |
| Respiratory Rate (xxx)              | 16 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 111 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 73 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3532002

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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



US3532002

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:14

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 8 SEP 2020

What was the treatment time? (00:00-23:59) 08:40 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 08:40

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

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3532002

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:14

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 8 SEP 2020                           |
| Collection time ( <i>00:00-23:59</i> ) | 08:07 (24 HR)                        |
| Collection date and time (derived)     | 8 SEP 2020 08:07                     |

US3532002

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:34:14

| Collection date (dd MMM yyyy) |                           |                                 | 8 SEP 2020                         |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 07:51                           | 8 SEP 2020 07:51                   |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3532002

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.2 °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 08 SEP 2020 09:16

PC Open Date & Time 08 SEP 2020 09:00

PC Close Date & Time 08 SEP 2020 11:30

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**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 97.6 °F

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 08 SEP 2020 19:06 |
| PC Open Date & Time  | 08 SEP 2020 12:25 |
| PC Close Date & Time | 09 SEP 2020 11:59 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:34:14

**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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 16:53

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 16:12

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59



US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

11 SEP 2020 21:34

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:34:14

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

12 SEP 2020 16:56

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:34:14

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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

97.9 °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

13 SEP 2020 18:56

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**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

98.0 °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

14 SEP 2020 18:07

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**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

08 SEP 2020 09:16

PC Open Date & Time

08 SEP 2020 09:00

PC Close Date & Time

08 SEP 2020 11:30

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

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

4

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 19:12

PC Open Date & Time

08 SEP 2020 12:25

PC Close Date & Time

09 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:34:14

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

5

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

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

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

09 SEP 2020 16:56

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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

5

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

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

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

10 SEP 2020 16:13

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59



US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:34:14

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

30

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

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

11 SEP 2020 21:36

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**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

12 SEP 2020 16:56

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**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

13 SEP 2020 18:56

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**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

14 SEP 2020 18:07

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**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 ☐

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 08 SEP 2020 09:17 |
| PC Open Date & Time  | 08 SEP 2020 09:00 |
| PC Close Date & Time | 08 SEP 2020 11:30 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**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 ☐

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 08 SEP 2020 19:13 |
| PC Open Date & Time  | 08 SEP 2020 12:25 |
| PC Close Date & Time | 09 SEP 2020 11:59 |



US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

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 ☒

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 09 SEP 2020 16:57 |
| PC Open Date & Time          | 09 SEP 2020 12:00 |
| PC Close Date & Time         | 10 SEP 2020 11:59 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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 ☒

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 10 SEP 2020 16:14 |
| PC Open Date & Time          | 10 SEP 2020 12:00 |
| PC Close Date & Time         | 11 SEP 2020 11:59 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**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 ☒

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 11 SEP 2020 21:36 |
| PC Open Date & Time          | 11 SEP 2020 12:00 |
| PC Close Date & Time         | 12 SEP 2020 11:59 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

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 ☐

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

|                      |                   |                              |
|----------------------|-------------------|------------------------------|
|                      |                   | Yes <input type="checkbox"/> |
| PC Time stamp        | 12 SEP 2020 16:57 |                              |
| PC Open Date & Time  | 12 SEP 2020 12:00 |                              |
| PC Close Date & Time | 13 SEP 2020 11:59 |                              |



US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

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 ☒

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 13 SEP 2020 18:57 |
| PC Open Date & Time          | 13 SEP 2020 12:00 |
| PC Close Date & Time         | 14 SEP 2020 11:59 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

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 ☒

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 14 SEP 2020 18:08 |
| PC Open Date & Time          | 14 SEP 2020 12:00 |
| PC Close Date & Time         | 15 SEP 2020 11:59 |

US3532002

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3532002

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:14

Was Contact Attempted?

Yes ☒

No ☐

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

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3532002

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3532002

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3532002

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:14

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 12 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                                  |

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:14

|                                           |                                       |
|-------------------------------------------|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|                                           | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 12 OCT 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 12:33 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 12 OCT 2020 12:33                     |
| Temperature ( <i>xxx.x</i> )              | 97.6 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|                                           | Axillary <input type="radio"/>        |
|                                           | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 72 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 20 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 146 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 86 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3532002

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:14

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.*

US3532002

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:14

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 12 OCT 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 12:47 (24 HR)                        |
| Collection date and time (derived)     | 12 OCT 2020 12:47                    |

US3532002

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 OCT 2020 20:27:53

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59



US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**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

18 OCT 2020 00:02:18

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**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

26 OCT 2020 14:15:48

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

DAY 92

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

08 NOV 2020 15:16:35

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

DAY 99

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

15 NOV 2020 18:53:04

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2020 23:59



US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| TIMEPOINT                                                                                                                                                                       | DAY 96                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59



US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 18:59:04

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**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 ☐ 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 ☐



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**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 ☐ 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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**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 ☐ 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 ☐



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

TIMEPOINT

DAY 208

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

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**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |



US3532002

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

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**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

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**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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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](#)

22 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

DAY 313

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

DAY 474

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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06 JAN 2022 00:01

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10 JAN 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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17 JAN 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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

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US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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31 JAN 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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

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US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3532002

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

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

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

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US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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 ☐

US3532002

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

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**Generated On: 26 Nov 2020 09:34:14**

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

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

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28 FEB 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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

Date and time of submission

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07 MAR 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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 ☐



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

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

Date and time of submission

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US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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

US3532002

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

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

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

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US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

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

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

Date and time of submission

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Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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 ☐



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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 ☐ 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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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 ☐ 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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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 ☐



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 JUN 2022 00:01

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20 JUN 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 JUN 2022 00:01

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27 JUN 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 JUN 2022 00:01

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04 JUL 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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

Date and time of submission

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07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 JUL 2022 00:01

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25 JUL 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**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 ☐ 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 ☐

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| TIMEPOINT                                                                                                                                                                       | DAY 775                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

| 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"/>                                               |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3532002

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:14

Was Contact Attempted?

Yes ☒

No ☐

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

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3532002

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:14

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*

US3532002

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:14

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3532002

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:34:14

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

US3532002

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:34:14

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3532002

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:34:14

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:14

AEID

Adverse event

WORSENING BACK PAIN

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

5 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

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 ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

v6.020 DTW (1102)

350 of 2036

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:14

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



US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:14

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US077-2020-MRNA-1273-P30<br>1000003                                                                                                                          |
| Adverse event                                                  | WORSENING BACK PAIN                                                                                                                                              |
| 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)                                       | 8 SEP 2020                                                                                                                                                       |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 14 OCT 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input 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 SEP 2020                                                                                                                                                      |
| Hospital Discharge Date (dd MMM yyyy)                          | 18 SEP 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)                                              | 352 of 2036                                                                                                                                                      |

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:14

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                        | True                                                                                                                                                                                                                                                                            |
| 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                                                                    |                                                                                                                                                                                                                                                                                 |

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:14

---

DUE TO UNDERLYING BACK  
PROBLEMS AND UNRELATED  
TO VACCINE. HE HAD A  
TRANSFORAMINAL LUMBER  
INTERBODY FUSION OF HIS  
SPINE DUE TO DEGENERATIVE  
DISK DISEASE IN HIS BACK (AN  
UNDERLYING MEDICAL  
HISTORY PROBLEM).  
HOSPITALIZED AFTER  
SURGERY.

---

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

---

US3532002

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

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

**Generated On: 26 Nov 2020 09:34:14**

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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.**

---

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:14

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | FENOFIBRATE                                                                                                                                                                                                                                                                                                                                                                                                              |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | ELEVATED CHOLESTEROL                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose per administration        | 145                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 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"/>                                                                                                                                                                                            |

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:14

|                                                                   |                          |                                      |
|-------------------------------------------------------------------|--------------------------|--------------------------------------|
|                                                                   | 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) <input type="text"/>                     |                          |                                      |
| <hr/>                                                             |                          |                                      |
| Start date completely unknown                                     |                          | True                                 |
| 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"/> |

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:14

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | CARVEDILOL                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HYPERTENSION                                                                                                                                                                                                                                                                                                                                                                                                             |
| Dose per administration        | 6.25                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 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 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"/>                                                                                                                                                                                            |

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:14

|                                                                   |                          |                                      |
|-------------------------------------------------------------------|--------------------------|--------------------------------------|
|                                                                   | 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) <input type="text"/>                     |                          |                                      |
| <hr/>                                                             |                          |                                      |
| Start date completely unknown                                     |                          | True                                 |
| 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"/> |



US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:14

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | AMLODIPINE                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HYPERTENSION                                                                                                                                                                                                                                                                                                                                                                                                             |
| 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"/>                                                                                                                                                                                            |

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:14

|                                                                   |                          |                                      |
|-------------------------------------------------------------------|--------------------------|--------------------------------------|
|                                                                   | 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) <input type="text"/>                     |                          |                                      |
| <hr/>                                                             |                          |                                      |
| Start date completely unknown                                     |                          | True                                 |
| 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 09:34:14

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | LOSARTAN                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | HYPERTENSION                                                                                                                                                                                                                                                                                                                                                                                                             |
| Dose per administration              | 100                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 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"/>                                                                                                                                                                                            |

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:14

|                                                                   |                          |                                      |
|-------------------------------------------------------------------|--------------------------|--------------------------------------|
|                                                                   | 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) <input type="text"/>                     |                          |                                      |
| <hr/>                                                             |                          |                                      |
| Start date completely unknown                                     |                          | True                                 |
| 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 09:34:14

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | BABY ASPIRIN                                                                                                                                                                                                                                                                                                                                                                                                             |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | GENERAL HEART HEALTH                                                                                                                                                                                                                                                                                                                                                                                                     |
| 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 (5)

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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"/>             |
| If route of administration is Other, specify _____ |                                      |
| Start date (dd MMM yyyy)                           | UN UNK 2016                          |
| 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | ROSUVASTATIN                                                                                                                                                                                                                                                                                                                                                                                                             |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | ELEVATED CHOLESTEROL                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose per administration              | 20                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 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) <input type="text"/>                     |                          |                                      |
| <hr/>                                                             |                          |                                      |
| Start date completely unknown                                     |                          | True                                 |
| 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)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | OZEMPIC                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | TYPE 2 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 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 checked="" type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input checked="" type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:14

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input checked="" type="radio"/> |
|                                                                   | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | METFORMIN                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Prophylaxis                    | Yes <input type="checkbox"/><br>No <input checked="" type="checkbox"/>                                                                                                                                                                                                                                                                                                                                                                                    |
| Indication                     | TYPE 2 DIABETES                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Dose per administration        | 750                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                      | mg <input checked="" type="checkbox"/><br>ug <input type="checkbox"/><br>mL <input type="checkbox"/><br>g <input type="checkbox"/><br>IU <input type="checkbox"/><br>tablet <input type="checkbox"/><br>capsule <input type="checkbox"/><br>puff <input type="checkbox"/><br>Other <input type="checkbox"/>                                                                                                                                               |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Frequency                      | once daily <input type="checkbox"/><br>twice daily <input checked="" type="checkbox"/><br>three times daily <input type="checkbox"/><br>four times daily <input type="checkbox"/><br>every other day <input type="checkbox"/><br>every week <input type="checkbox"/><br>every month <input type="checkbox"/><br>as needed <input type="checkbox"/><br>once <input type="checkbox"/><br>unknown <input type="checkbox"/><br>other <input type="checkbox"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Route of administration        | Oral <input checked="" type="checkbox"/><br>Topical <input type="checkbox"/><br>Subcutaneous <input type="checkbox"/><br>Transdermal <input type="checkbox"/><br>Intraocular <input type="checkbox"/><br>Intramuscular <input type="checkbox"/>                                                                                                                                                                                                           |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                                   | Intralesional            | <input type="checkbox"/>         |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>         |
|                                                                   | Nasal                    | <input type="checkbox"/>         |
|                                                                   | Vaginal                  | <input type="checkbox"/>         |
|                                                                   | Rectal                   | <input type="checkbox"/>         |
|                                                                   | Intravenous              | <input type="checkbox"/>         |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>         |
|                                                                   | Other                    | <input type="checkbox"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          | UN                       | UNK 2016                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 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 (9)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | LEVOTHYROXINE                                                                                                                                                                                                                                                                                                                                                                                                            |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HYPOTHYROIDISM                                                                                                                                                                                                                                                                                                                                                                                                           |
| Dose per administration        | 50                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                      | mg <input type="radio"/><br>ug <input checked="" 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)

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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"/>             |
| If route of administration is Other, specify _____ |                                      |
| Start date (dd MMM yyyy)                           | UN UNK 1985                          |
| 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (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)                                          |                          | 10 SEP 2020                         |
| Start date completely unknown                                     |                          | False                               |
| Ongoing?                                                          | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            |                          | 10 SEP 2020                         |
| <hr/>                                                             |                          |                                     |
| Was this medication taken for solicited event?                    | Yes                      | <input checked="" type="checkbox"/> |
|                                                                   | No                       | <input type="checkbox"/>            |
| <hr/>                                                             |                          |                                     |
| Separate Dosage Number (derived)                                  |                          | <input type="text"/>                |
| Interval Dosage Unit Number (derived)                             |                          | <input type="text"/>                |
| Interval Dosage Definition (derived)                              |                          | 802 <input type="checkbox"/>        |
|                                                                   |                          | 803 <input type="checkbox"/>        |
|                                                                   |                          | 804 <input type="checkbox"/>        |



US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:14

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

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:34:14

|                                                    |                          |                                     |
|----------------------------------------------------|--------------------------|-------------------------------------|
|                                                    | Respiratory (Inhalation) | <input type="checkbox"/>            |
|                                                    | Intralesional            | <input type="checkbox"/>            |
|                                                    | Intraperitoneal          | <input type="checkbox"/>            |
|                                                    | Nasal                    | <input type="checkbox"/>            |
|                                                    | Vaginal                  | <input type="checkbox"/>            |
|                                                    | Rectal                   | <input type="checkbox"/>            |
|                                                    | Intravenous              | <input type="checkbox"/>            |
|                                                    | Intravenous Bolus        | <input type="checkbox"/>            |
|                                                    | Intravenous Drip         | <input type="checkbox"/>            |
|                                                    | Other                    | <input type="checkbox"/>            |
| <hr/>                                              |                          |                                     |
| If route of administration is Other, specify <hr/> |                          |                                     |
| Start date (dd MMM yyyy)                           | UN AUG 2020              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?                                           | Yes                      | <input type="checkbox"/>            |
|                                                    | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                              |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)             | 14 OCT 2020              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|                                                    | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                              |                          |                                     |
| Separate Dosage Number (derived)                   | <hr/>                    |                                     |
| Interval Dosage Unit Number (derived)              | <hr/>                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|                                                    | 803                      | <input type="checkbox"/>            |
|                                                    | 804                      | <input type="checkbox"/>            |

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:14

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | PERCOCET                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | WORSENING BACK PAIN                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose per administration        | 10/325                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 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 type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input checked="" type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | EVERY 6 HOURS<br>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"/>                                                                                                                                                                           |

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:14

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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)                                          |                          | 17 SEP 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 (13)

Generated On: 26 Nov 2020 09:34:14

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:14

|                                                                   |                          |                                     |
|-------------------------------------------------------------------|--------------------------|-------------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>            |
|                                                                   | Intralesional            | <input type="checkbox"/>            |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>            |
|                                                                   | Nasal                    | <input type="checkbox"/>            |
|                                                                   | Vaginal                  | <input type="checkbox"/>            |
|                                                                   | Rectal                   | <input type="checkbox"/>            |
|                                                                   | Intravenous              | <input type="checkbox"/>            |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>            |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>            |
|                                                                   | Other                    | <input type="checkbox"/>            |
| <hr/>                                                             |                          |                                     |
| If route of administration is Other, specify <input type="text"/> |                          |                                     |
| <hr/>                                                             |                          |                                     |
| Start date (dd MMM yyyy)                                          |                          | 16 OCT 2020                         |
| Start date completely unknown                                     |                          | False                               |
| Ongoing?                                                          | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            |                          | 16 OCT 2020                         |
| <hr/>                                                             |                          |                                     |
| Was this medication taken for solicited event?                    | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| Separate Dosage Number (derived)                                  | <input type="text"/>     |                                     |
| Interval Dosage Unit Number (derived)                             | <input type="text"/>     |                                     |
| Interval Dosage Definition (derived)                              | 802                      | <input type="checkbox"/>            |
|                                                                   | 803                      | <input type="checkbox"/>            |
|                                                                   | 804                      | <input type="checkbox"/>            |

US3532002

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 09:34:14**

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

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

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**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures**

**Generated On: 26 Nov 2020 09:34:14**

| Procedure/Surgery date ( <i>dd MMM<br/>yyyy</i> ) | Procedure/Surgery                         | Indication    | If indication is Other, specify |
|---------------------------------------------------|-------------------------------------------|---------------|---------------------------------|
| 16 SEP 2020                                       | TRANSFORAMINAL LUMBAR<br>INTERBODY FUSION | Adverse Event |                                 |



US3532002

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:34:14

---

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

---

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:34:14

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 ☐

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

|                                                                |                                                               |
|----------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                          | USA-US077-2020-MRNA-1273-P301000003                           |
| Serious                                                        | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death                                                          | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening                                               | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity             | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                             | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event                                | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name                                      | EVAN                                                          |
| Investigator's Last Name                                       | ANDERSON                                                      |
| Site Address: Street                                           | 2015 UPPERGATE DRIVE                                          |
| Site Address: City                                             | ATLANTA                                                       |
| Site Address: State                                            | GA                                                            |
| Site Address: Postal Code                                      | 30323                                                         |
| Investigator Country                                           | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                             | 5                                                             |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:34:14

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US077-2020-MRNA-1273-P301000003                              |
| 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                                                                                                                                                                     | EVAN                                                             |
| Investigator's Last Name                                                                                                                                                                      | ANDERSON                                                         |
| Site Address: Street                                                                                                                                                                          | 2015 UPPERGATE DRIVE                                             |
| Site Address: City                                                                                                                                                                            | ATLANTA                                                          |
| Site Address: State                                                                                                                                                                           | GA                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 30323                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 23/SEP/2020 08:32                                                |
| 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                                                             |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:34:14

|                                                                                                                                                                                               |                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US077-2020-MRNA-1273-P301000003                           |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | EVAN                                                          |
| Investigator's Last Name                                                                                                                                                                      | ANDERSON                                                      |
| Site Address: Street                                                                                                                                                                          | 2015 UPPERGATE DRIVE                                          |
| Site Address: City                                                                                                                                                                            | ATLANTA                                                       |
| Site Address: State                                                                                                                                                                           | GA                                                            |
| Site Address: Postal Code                                                                                                                                                                     | 30323                                                         |
| Investigator Country                                                                                                                                                                          | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                             |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 21/OCT/2020 17:45                                             |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True                                                          |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:34:14

|                                                                                                                                                                                               |                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US077-2020-MRNA-1273-P301000003                           |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | EVAN                                                          |
| Investigator's Last Name                                                                                                                                                                      | ANDERSON                                                      |
| Site Address: Street                                                                                                                                                                          | 2015 UPPERGATE DRIVE                                          |
| Site Address: City                                                                                                                                                                            | ATLANTA                                                       |
| Site Address: State                                                                                                                                                                           | GA                                                            |
| Site Address: Postal Code                                                                                                                                                                     | 30323                                                         |
| Investigator Country                                                                                                                                                                          | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                             |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 26/OCT/2020 15:12                                             |
| 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                                                          |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:34:14

|                                                                                                                                                                                               |                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US077-2020-MRNA-1273-P301000003                           |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | EVAN                                                          |
| Investigator's Last Name                                                                                                                                                                      | ANDERSON                                                      |
| Site Address: Street                                                                                                                                                                          | 2015 UPPERGATE DRIVE                                          |
| Site Address: City                                                                                                                                                                            | ATLANTA                                                       |
| Site Address: State                                                                                                                                                                           | GA                                                            |
| Site Address: Postal Code                                                                                                                                                                     | 30323                                                         |
| Investigator Country                                                                                                                                                                          | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                             |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 29/OCT/2020 19:04                                             |
| 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                                                          |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:34:14

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US077-2020-MRNA-1273-P301000003                              |
| 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                                                                                                                                                                     | EVAN                                                             |
| Investigator's Last Name                                                                                                                                                                      | ANDERSON                                                         |
| Site Address: Street                                                                                                                                                                          | 2015 UPPERGATE DRIVE                                             |
| Site Address: City                                                                                                                                                                            | ATLANTA                                                          |
| Site Address: State                                                                                                                                                                           | GA                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 30323                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 03/NOV/2020 08:16                                                |
| 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

US3532002 (Prod: Children's Healthcare of Atlanta)

US3532002

**Form: Participant Creation**

**Generated On: 26 Nov 2020 09:34:14**

[Participant ID](#)

| Audit                    | User                                            | Time (GMT)           |
|--------------------------|-------------------------------------------------|----------------------|
| User entered 'US3532002' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 11 Aug 2020 18:49:45 |

US3532002

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:34:14**

[Was this visit performed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:43:53 |

US3532002

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                                            | Time (GMT)           |
|----------------------------|-------------------------------------------------|----------------------|
| User entered '11 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 11 Aug 2020 18:49:46 |

US3532002

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:43:53 |

US3532002

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:34:14**

[Folder OID](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 11 Aug 2020 19:43:53 |

US3532002

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                                           | Time (GMT)           |
|----------------------------|------------------------------------------------|----------------------|
| User entered (b) (6) 1956' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 11 Aug 2020 18:49:47 |

US3532002

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:14

[Age](#)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '63' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:44:11 |



US3532002

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:34:14**

[Age Units](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 11 Aug 2020 19:44:11 |

US3532002

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:34:14**

[Age \(Derived\)](#)

| Audit             | User   | Time (GMT)           |
|-------------------|--------|----------------------|
| User entered '64' | System | 11 Aug 2020 19:45:05 |

US3532002

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:34:14**

[Sex](#)

| Audit                   | User                           | Time (GMT)           |
|-------------------------|--------------------------------|----------------------|
| User entered 'Male (M)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:44:11 |

US3532002

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:34:14**

[Ethnicity](#)

| Audit                                                          | User                | Time (GMT)           |
|----------------------------------------------------------------|---------------------|----------------------|
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Etza Peters (b) (4) | 11 Aug 2020 19:44:11 |

US3532002

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:34:14**

[White](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '1' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:44:11 |

US3532002

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:34:14**

[Black](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:44:11 |

US3532002

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:14

[Asian](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:44:11 |

US3532002

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:34:14**

[American Indian or Alaska Native](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:44:11 |



US3532002

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:34:14**

[Native Hawaiian or other Pacific Islander](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:44:11 |

US3532002

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:34:14**

[Other](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:44:11 |

US3532002

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:34:14**

[If race is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:44:11 |

US3532002

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:34:14**

[Unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:44:11 |

US3532002

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:34:14**

[Not reported](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:44:11 |

US3532002

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '11 Aug 2020' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:45:05 |

US3532002

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Aug 2020' | System | 11 Aug 2020 19:45:05 |

US3532002

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 11 Aug 2020 19:45:05 |



US3532002

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:34:14**

[Protocol Version](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'Amendment 2 (2)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:45:05 |

US3532002

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 22:06:44 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 11 Aug 2020 22:06:44 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | Etza Peters (b) (4) | 11 Aug 2020 22:06:44 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 19:45:05 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 11 Aug 2020 19:45:05 |

US3532002

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:45:05 |

US3532002

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:34:14**

If reason for screen fail is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:45:05 |

US3532002

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:34:14**

[Was this participant screened previously?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:45:05 |

US3532002

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:34:14**

[If Yes, previous participant number](#)

| Audit               | User                                           | Time (GMT)           |
|---------------------|------------------------------------------------|----------------------|
| User entered empty. | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 11 Aug 2020 18:49:46 |

US3532002

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:34:14**

[Enrollment Trigger](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1'    | System | 11 Aug 2020 22:06:44 |
| User entered empty. | System | 11 Aug 2020 21:50:24 |

US3532002

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 21:50:24 |



US3532002

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 09:34:14**

[Were any significant conditions reported?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:46:30 |

US3532002

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:14

[Condition](#)

| Audit                                                                                                                                                                                          | User                 | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Aug 2020 22:49:12 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                   | Coder Import (b) (4) | 11 Aug 2020 22:49:12 |
| Data point term sent to Coder                                                                                                                                                                  | System               | 11 Aug 2020 22:48:19 |
| User entered 'Hypertension'                                                                                                                                                                    | Etza Peters (b) (4)  | 11 Aug 2020 22:47:24 |

US3532002

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 1990' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:47:24 |

US3532002

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:47:24 |

US3532002

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Condition ongoing at study entry](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:47:24 |

US3532002

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:47:24 |

US3532002

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:47:24 |

US3532002

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1990' | System | 11 Aug 2020 22:47:24 |



US3532002

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1990' | System | 11 Aug 2020 22:47:24 |

US3532002

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 22:47:24 |

US3532002

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 22:47:24 |

US3532002

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:14

[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) | 11 Aug 2020 22:49:12 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                               | Coder Import (b) (4) | 11 Aug 2020 22:49:12 |
| Data point term sent to Coder                                                                                                                                                                                                                             | System               | 11 Aug 2020 22:48:20 |
| User entered 'Type 2 Diabetes'                                                                                                                                                                                                                            | Etza Peters (b) (4)  | 11 Aug 2020 22:47:54 |

US3532002

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 2012' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:47:54 |

US3532002

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:47:54 |

US3532002

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Condition ongoing at study entry](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:47:54 |

US3532002

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:47:54 |



US3532002

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:47:54 |

US3532002

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2012' | System | 11 Aug 2020 22:47:54 |

US3532002

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2012' | System | 11 Aug 2020 22:47:54 |

US3532002

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 22:47:54 |

US3532002

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 22:47:54 |

US3532002

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:14

Condition

| Audit                                                                                                                                                                                                                                                                                                   | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).             | (b) (4), (b) (6)     | 30 Oct 2020 06:32:26 |
| User coded data point as SOC: Eye disorders, HLGT: Coder Import (b) (4) Glaucoma and ocular hypertension, HLT: Glaucomas (b) (4) (excl congenital), PT: Glaucoma, LLT: Glaucoma both eyes - version MedDRA\23.0.                                                                                        | (b) (4)              | 26 Oct 2020 19:21:31 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                                             | Coder Import (b) (4) | 26 Oct 2020 19:21:31 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                           | System               | 26 Oct 2020 18:15:07 |
| Query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM). | Etza Peters (b) (4)  | 26 Oct 2020 18:14:24 |
| Coding entries removed.                                                                                                                                                                                                                                                                                 | Etza Peters (b) (4)  | 26 Oct 2020 18:14:18 |
| User entered 'Bilateral GLAUCOMA' reason for change: Data Entry Error                                                                                                                                                                                                                                   | Etza Peters (b) (4)  | 26 Oct 2020 18:14:18 |
| User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).                       | (b) (4), (b) (6)     | 23 Oct 2020 08:41:02 |
| Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'N meds taken' (Site from DM).      | Etza Peters (b) (4)  | 20 Oct 2020 16:44:18 |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).                       | (b) (4), (b) (6)     | 29 Sep 2020 10:49:34 |

US3532002

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:14

[Condition](#)

| Audit                                                                                                                                                                                                                                                                                       | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User opened query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM). | (b) (4), (b) (6)     | 29 Sep 2020 10:47:31 |
| User coded data point as SOC: Eye disorders, HLGT: Coder Import Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\\23.0.                                                                                                     | (b) (4)              | 11 Aug 2020 22:50:13 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                                                                                | Coder Import (b) (4) | 11 Aug 2020 22:50:13 |
| Data point term sent to Coder                                                                                                                                                                                                                                                               | System               | 11 Aug 2020 22:49:21 |
| User entered 'Glaucoma'                                                                                                                                                                                                                                                                     | Etza Peters (b) (4)  | 11 Aug 2020 22:48:23 |
|                                                                                                                                                                                                                                                                                             | (b) (4)              |                      |

US3532002

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 1977' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:48:23 |



US3532002

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:48:23 |

US3532002

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Condition ongoing at study entry](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:48:23 |

US3532002

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:48:23 |

US3532002

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:48:23 |

US3532002

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1977' | System | 11 Aug 2020 22:48:23 |

US3532002

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1977' | System | 11 Aug 2020 22:48:23 |

US3532002

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 22:48:23 |

US3532002

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 22:48:23 |



US3532002

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:14

[Condition](#)

| Audit                                                                                                                                                                         | User                 | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: Cholesterol high - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Aug 2020 22:51:14 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                  | Coder Import (b) (4) | 11 Aug 2020 22:51:14 |
| Data point term sent to Coder                                                                                                                                                 | System               | 11 Aug 2020 22:50:24 |
| User entered 'Elevated Cholesterol'                                                                                                                                           | Etza Peters (b) (4)  | 11 Aug 2020 22:49:25 |

US3532002

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 1990' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:49:25 |

US3532002

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:49:25 |

US3532002

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Condition ongoing at study entry](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:49:25 |

US3532002

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:49:25 |

US3532002

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:49:25 |

US3532002

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1990' | System | 11 Aug 2020 22:49:25 |

US3532002

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1990' | System | 11 Aug 2020 22:49:25 |



US3532002

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 22:49:25 |

US3532002

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 22:49:25 |

US3532002

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:14

[Condition](#)

| Audit                                                                                                                                                                                                                     | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Aug 2020 22:51:14 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                              | (b) (4)              | 11 Aug 2020 22:51:14 |
| Data point term sent to Coder                                                                                                                                                                                             | System               | 11 Aug 2020 22:50:24 |
| User entered 'Vasectomy'                                                                                                                                                                                                  | Etza Peters (b) (4)  | 11 Aug 2020 22:49:48 |
|                                                                                                                                                                                                                           | (b) (4)              |                      |

US3532002

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 1996' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:49:48 |

US3532002

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:49:48 |

US3532002

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:14

[Condition ongoing at study entry](#)

| Audit                                                                                                                                                                                                                                           | User                | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.<br>' (Site from DM).             | (b) (4), (b) (6)    | 22 Oct 2020 05:42:21 |
| Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.<br>' answered with 'updated' (Site from DM). | Etza Peters (b) (4) | 20 Oct 2020 16:43:13 |
| User entered 'No (N)' reason for change: Data Entry Error                                                                                                                                                                                       | Etza Peters (b) (4) | 20 Oct 2020 16:42:42 |
| User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.<br>' (Site from DM).             | (b) (4), (b) (6)    | 29 Sep 2020 10:51:38 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                          | Etza Peters (b) (4) | 11 Aug 2020 22:49:48 |

US3532002

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                                         | User                | Time (GMT)           |
|-----------------------------------------------|---------------------|----------------------|
| User entered 'un UNK 1996' reason for change: | Etza Peters (b) (4) | 20 Oct 2020 16:42:42 |
| Data Entry Error                              | (b) (4)             |                      |
| User entered empty.                           | Etza Peters (b) (4) | 11 Aug 2020 22:49:48 |
|                                               | (b) (4)             |                      |

US3532002

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:34:14**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:49:48 |



US3532002

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1996' | System | 11 Aug 2020 22:49:48 |

US3532002

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1996' | System | 11 Aug 2020 22:49:48 |

US3532002

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1996' | System | 20 Oct 2020 16:42:42 |
| User entered empty.     | System | 11 Aug 2020 22:49:48 |

US3532002

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1996' | System | 20 Oct 2020 16:42:42 |
| User entered empty. | System | 11 Aug 2020 22:49:48 |

US3532002

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:14

[Condition](#)

| Audit                                                                                                                                                                                                                                                   | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal laminectomy, LLT: Lumbar laminectomy - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 12 Aug 2020 10:28:28 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                                                                 | Coder Import (b) (4)<br>(b) (4) | 12 Aug 2020 10:28:28 |
| Data point term sent to Coder                                                                                                                                                                                                                           | System                          | 11 Aug 2020 22:52:25 |
| User entered 'Back Surgery Lumbar Laminectomy'                                                                                                                                                                                                          | Etza Peters (b) (4)<br>(b) (4)  | 11 Aug 2020 22:51:39 |

US3532002

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un Dec 2019' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:51:39 |

US3532002

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:51:39 |

US3532002

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:34:14**

[Condition ongoing at study entry](#)

| Audit                                                     | User                | Time (GMT)           |
|-----------------------------------------------------------|---------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | Etza Peters (b) (4) | 11 Aug 2020 23:02:27 |
| User entered 'Yes (Y)'                                    | Etza Peters (b) (4) | 11 Aug 2020 22:51:39 |



US3532002

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                                                          | User                | Time (GMT)           |
|----------------------------------------------------------------|---------------------|----------------------|
| User entered 'un Dec 2019' reason for change: Data Entry Error | Etza Peters (b) (4) | 11 Aug 2020 23:02:27 |
| User entered empty.                                            | Etza Peters (b) (4) | 11 Aug 2020 22:51:39 |

US3532002

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:34:14**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:51:39 |

US3532002

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Dec 2019' | System | 11 Aug 2020 22:51:39 |

US3532002

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2019' | System | 11 Aug 2020 22:51:39 |

US3532002

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Dec 2019' | System | 11 Aug 2020 23:02:27 |
| User entered empty.     | System | 11 Aug 2020 22:51:39 |

US3532002

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2019' | System | 11 Aug 2020 23:02:27 |
| User entered empty. | System | 11 Aug 2020 22:51:39 |

US3532002

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:14

Condition

| Audit                                                                                                                                                                                                                                                                                                               | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral ROTATOR CUFF. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.<br>' (Site from DM).             | (b) (4), (b) (6)     | 28 Oct 2020 07:09:47 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\23.0.                                                                                                    | Coder Import (b) (4) | 26 Oct 2020 19:21:32 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                                                         | Coder Import (b) (4) | 26 Oct 2020 19:21:32 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                       | System               | 26 Oct 2020 18:15:08 |
| Query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral ROTATOR CUFF. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.<br>' answered with 'updated' (Site from DM). | Etza Peters (b) (4)  | 26 Oct 2020 18:14:46 |
| Coding entries removed.                                                                                                                                                                                                                                                                                             | Etza Peters (b) (4)  | 26 Oct 2020 18:14:41 |
| User entered 'Right ROTATOR CUFF TEAR' reason for change: Data Entry Error                                                                                                                                                                                                                                          | Etza Peters (b) (4)  | 26 Oct 2020 18:14:41 |
| User opened query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral ROTATOR CUFF. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.<br>' (Site from DM).             | (b) (4), (b) (6)     | 29 Sep 2020 10:51:23 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\23.0.                                                                                                    | Coder Import (b) (4) | 11 Aug 2020 23:20:15 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                                                         | Coder Import (b) (4) | 11 Aug 2020 23:20:15 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                       | System               | 11 Aug 2020 23:19:05 |

US3532002

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:34:14**

[Condition](#)

| Audit                            | User                           | Time (GMT)           |
|----------------------------------|--------------------------------|----------------------|
| User entered 'Rotator Cuff Tear' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:18:47 |



US3532002

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 2004' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:18:47 |

US3532002

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:18:47 |

US3532002

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:14

[Condition ongoing at study entry](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:19:58 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 11 Aug 2020 23:19:58 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Etza Peters (b) (4) | 11 Aug 2020 23:19:58 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:18:47 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 11 Aug 2020 23:18:47 |

US3532002

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 2005' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:18:47 |

US3532002

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:34:14**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:18:47 |

US3532002

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2004' | System | 11 Aug 2020 23:18:47 |

US3532002

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2004' | System | 11 Aug 2020 23:18:47 |

US3532002

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2005' | System | 11 Aug 2020 23:18:47 |



US3532002

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2005' | System | 11 Aug 2020 23:18:47 |

US3532002

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:14

Condition

| Audit                                                                                                                                                                                                                                                                                                               | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral ROTATOR CUFF. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.<br>' (Site from DM).             | (b) (4), (b) (6)     | 28 Oct 2020 07:09:58 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\23.0.                                                                                             | Coder Import (b) (4) | 26 Oct 2020 19:21:32 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                                                         | Coder Import (b) (4) | 26 Oct 2020 19:21:32 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                       | System               | 26 Oct 2020 18:16:09 |
| Query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral ROTATOR CUFF. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.<br>' answered with 'updated' (Site from DM). | Etza Peters (b) (4)  | 26 Oct 2020 18:15:34 |
| Coding entries removed.                                                                                                                                                                                                                                                                                             | Etza Peters (b) (4)  | 26 Oct 2020 18:15:27 |
| User entered 'Right ROTATOR CUFF REPAIR' reason for change: Data Entry Error                                                                                                                                                                                                                                        | Etza Peters (b) (4)  | 26 Oct 2020 18:15:27 |
| User opened query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral ROTATOR CUFF. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.<br>' (Site from DM).             | (b) (4), (b) (6)     | 29 Sep 2020 10:51:12 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\23.0.                                                                                             | Coder Import (b) (4) | 11 Aug 2020 23:21:16 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                                                         | Coder Import (b) (4) | 11 Aug 2020 23:21:16 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                       | System               | 11 Aug 2020 23:20:06 |

US3532002

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:14

[Condition](#)

| Audit                                                                                                                                                                                                             | User                 | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Coding entries removed.                                                                                                                                                                                           | Etza Peters (b) (4)  | 11 Aug 2020 23:19:22 |
|                                                                                                                                                                                                                   | (b) (4)              |                      |
| User entered 'ROTATOR CUFF Repair' reason for change: Data Entry Error                                                                                                                                            | Etza Peters (b) (4)  | 11 Aug 2020 23:19:22 |
|                                                                                                                                                                                                                   | (b) (4)              |                      |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Aug 2020 23:05:17 |
|                                                                                                                                                                                                                   | (b) (4)              |                      |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                      | Coder Import (b) (4) | 11 Aug 2020 23:05:17 |
|                                                                                                                                                                                                                   | (b) (4)              |                      |
| Data point term sent to Coder                                                                                                                                                                                     | System               | 11 Aug 2020 23:03:41 |
| User entered 'Rotator Cuff Tear'                                                                                                                                                                                  | Etza Peters (b) (4)  | 11 Aug 2020 23:03:30 |
|                                                                                                                                                                                                                   | (b) (4)              |                      |

US3532002

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                                                             | User                           | Time (GMT)           |
|-------------------------------------------------------------------|--------------------------------|----------------------|
| User entered 'UN UNK 2005' reason for change:<br>Data Entry Error | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:19:22 |
| User entered 'un UNK 2004'                                        | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:03:30 |

US3532002

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:03:30 |

US3532002

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:14

[Condition ongoing at study entry](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:19:36 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 11 Aug 2020 23:19:36 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Etza Peters (b) (4) | 11 Aug 2020 23:19:36 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:03:30 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 11 Aug 2020 23:03:30 |

US3532002

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 2005' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:03:30 |

US3532002

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:34:14**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:03:30 |



US3532002

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2005' | System | 11 Aug 2020 23:19:22 |
| User entered 'Jan 2004' | System | 11 Aug 2020 23:03:30 |

US3532002

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2005' | System | 11 Aug 2020 23:19:22 |
| User entered '2004' | System | 11 Aug 2020 23:03:30 |

US3532002

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2005' | System | 11 Aug 2020 23:03:30 |

US3532002

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2005' | System | 11 Aug 2020 23:03:30 |

US3532002

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:14

[Condition](#)

| Audit                                                                                                                                                                                                                                            | User                            | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).                                | (b) (4), (b) (6)                | 28 Oct 2020 07:44:06 |
| Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'will update' (Site from DM).                | Etza Peters (b) (4)<br>(b) (4)  | 26 Oct 2020 18:15:59 |
| User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).                                | (b) (4), (b) (6)                | 29 Sep 2020 10:50:37 |
| User coded data point as SOC: Investigations, HLGT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy R knee - version MedDRA\23.0. | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 23:07:15 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                      | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 23:07:15 |
| Data point term sent to Coder                                                                                                                                                                                                                    | System                          | 11 Aug 2020 23:06:47 |
| User entered 'Right Knee Scope'                                                                                                                                                                                                                  | Etza Peters (b) (4)<br>(b) (4)  | 11 Aug 2020 23:06:04 |

US3532002

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 1984' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:06:04 |

US3532002

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:06:04 |

US3532002

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:14

[Condition ongoing at study entry](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:20:17 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 11 Aug 2020 23:20:17 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Etza Peters (b) (4) | 11 Aug 2020 23:20:17 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:06:04 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 11 Aug 2020 23:06:04 |



US3532002

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 1984' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:06:04 |

US3532002

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:34:14**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:06:04 |

US3532002

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1984' | System | 11 Aug 2020 23:06:04 |

US3532002

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1984' | System | 11 Aug 2020 23:06:04 |

US3532002

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1984' | System | 11 Aug 2020 23:06:04 |

US3532002

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1984' | System | 11 Aug 2020 23:06:04 |

US3532002

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:14

Condition

| Audit                                                                                                                                                                                                                                                                                                        | User                            | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Femur fracture, LLT: Femur fracture - version MedDRA\23.0.                                                                                             | Coder Import (b) (4)<br>(b) (4) | 12 Nov 2020 14:56:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                                                                                                                                       | Coder Import (b) (4)<br>(b) (4) | 12 Nov 2020 14:56:47 |
| User closed query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral FEMUR. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.<br>' (Site from DM).             | (b) (4), (b) (6)                | 22 Oct 2020 06:47:59 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                | System                          | 20 Oct 2020 16:49:31 |
| Query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral FEMUR. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.<br>' answered with 'updated' (Site from DM). | Etza Peters (b) (4)<br>(b) (4)  | 20 Oct 2020 16:48:52 |
| Coding entries removed.                                                                                                                                                                                                                                                                                      | Etza Peters (b) (4)<br>(b) (4)  | 20 Oct 2020 16:48:46 |
| User entered 'Right BROKEN FEMUR' reason for change: Data Entry Error                                                                                                                                                                                                                                        | Etza Peters (b) (4)<br>(b) (4)  | 20 Oct 2020 16:48:46 |
| User opened query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral FEMUR. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.<br>' (Site from DM).             | (b) (4), (b) (6)                | 29 Sep 2020 10:44:51 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Femur fracture, LLT: Fracture femur - version MedDRA\23.0.                                                                                             | Coder Import (b) (4)<br>(b) (4) | 12 Aug 2020 12:31:29 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                                                                                                                                       | Coder Import (b) (4)<br>(b) (4) | 12 Aug 2020 12:31:29 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                | System                          | 11 Aug 2020 23:08:48 |
| User entered 'Broken Femur'                                                                                                                                                                                                                                                                                  | Etza Peters (b) (4)<br>(b) (4)  | 11 Aug 2020 23:08:07 |

US3532002

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 1976' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:08:07 |



US3532002

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:08:07 |

US3532002

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:14

[Condition ongoing at study entry](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:20:38 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 11 Aug 2020 23:20:38 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Etza Peters (b) (4) | 11 Aug 2020 23:20:38 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:08:07 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 11 Aug 2020 23:08:07 |

US3532002

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                                                                                   | User                | Time (GMT)           |
|-----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System              | 11 Aug 2020 23:22:26 |
| User entered empty; reason for change Data Entry Error                                  | Etza Peters (b) (4) | 11 Aug 2020 23:22:26 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System              | 11 Aug 2020 23:08:07 |
| User entered 'un UNK ' (non-conformant).                                                | Etza Peters (b) (4) | 11 Aug 2020 23:08:07 |

US3532002

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '1' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:08:07 |

US3532002

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1976' | System | 11 Aug 2020 23:08:07 |

US3532002

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1976' | System | 11 Aug 2020 23:08:07 |

US3532002

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 23:08:07 |

US3532002

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 23:08:07 |



US3532002

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:14

[Condition](#)

| Audit                                                                                                                                                                                                                                                                                                     | User                            | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Bone operation, LLT: Bone operation - version MedDRA\23.0.                                                                                           | Coder Import (b) (4)<br>(b) (4) | 16 Nov 2020 14:44:50 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                                                                                                                                    | Coder Import (b) (4)<br>(b) (4) | 16 Nov 2020 14:44:50 |
| User closed query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral FEMUR. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).              | (b) (4), (b) (6)                | 23 Oct 2020 08:41:26 |
| User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).                                                                                          | (b) (4), (b) (6)                | 22 Oct 2020 04:16:45 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                             | System                          | 20 Oct 2020 16:50:34 |
| Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'in med hx' (Site from DM).                                                                            | Etza Peters (b) (4)<br>(b) (4)  | 20 Oct 2020 16:50:27 |
| Query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral FEMUR. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated ' (Site from DM). | Etza Peters (b) (4)<br>(b) (4)  | 20 Oct 2020 16:50:20 |
| Coding entries removed.                                                                                                                                                                                                                                                                                   | Etza Peters (b) (4)<br>(b) (4)  | 20 Oct 2020 16:50:14 |
| User entered 'Right FEMUR LENGTHENING SURGERY' reason for change: Data Entry Error                                                                                                                                                                                                                        | Etza Peters (b) (4)<br>(b) (4)  | 20 Oct 2020 16:50:14 |
| User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).                                                                                          | (b) (4), (b) (6)                | 29 Sep 2020 10:47:14 |

US3532002

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:14

[Condition](#)

| Audit                                                                                                                                                                                                                                                                                        | User                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User opened query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral FEMUR. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM). | (b) (4), (b) (6)     | 29 Sep 2020 10:46:05 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Bone operation, LLT: Bone operation - version MedDRA\23.0.                                                                             | Coder Import (b) (4) | 14 Aug 2020 08:22:33 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                                                                                                                       | (b) (4)              | 14 Aug 2020 08:22:33 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                | System               | 11 Aug 2020 23:09:50 |
| User entered 'Femur Lengthening Surgery'                                                                                                                                                                                                                                                     | Etza Peters (b) (4)  | 11 Aug 2020 23:08:56 |
|                                                                                                                                                                                                                                                                                              | (b) (4)              |                      |

US3532002

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 1997' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:08:56 |

US3532002

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:08:56 |

US3532002

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:34:14

[Condition ongoing at study entry](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:20:53 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 11 Aug 2020 23:20:53 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Etza Peters (b) (4) | 11 Aug 2020 23:20:53 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:08:56 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 11 Aug 2020 23:08:56 |

US3532002

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 1997' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:08:56 |

US3532002

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:34:14**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:08:56 |

US3532002

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1997' | System | 11 Aug 2020 23:08:56 |



US3532002

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1997' | System | 11 Aug 2020 23:08:56 |

US3532002

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1997' | System | 11 Aug 2020 23:08:56 |

US3532002

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1997' | System | 11 Aug 2020 23:08:56 |

US3532002

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:34:14

Condition

| Audit                                                                                                                                                                                                                                                                                                         | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.<br>' (Site from DM).               | (b) (4), (b) (6)     | 22 Oct 2020 02:49:05 |
| User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\23.0.                                                                                                          | (b) (4)              | 20 Oct 2020 16:48:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                                                   | Coder Import (b) (4) | 20 Oct 2020 16:48:48 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                 | System               | 20 Oct 2020 16:47:27 |
| Coding entries removed.                                                                                                                                                                                                                                                                                       | Etza Peters (b) (4)  | 20 Oct 2020 16:46:28 |
| User entered 'Bilateral CATARACTS' reason for change: Data Entry Error                                                                                                                                                                                                                                        | (b) (4)              |                      |
| Query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.<br>' answered with 'Bilateral' (Site from DM). | Etza Peters (b) (4)  | 20 Oct 2020 16:46:28 |
| User opened query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.<br>' (Site from DM).               | Etza Peters (b) (4)  | 20 Oct 2020 16:46:19 |
| User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\23.0.                                                                                                                    | (b) (4), (b) (6)     | 29 Sep 2020 10:45:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                                                   | (b) (4)              | 11 Aug 2020 23:11:19 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                 | System               | 11 Aug 2020 23:11:19 |
| User entered 'CATARACTS' reason for change: Data Entry Error                                                                                                                                                                                                                                                  | Etza Peters (b) (4)  | 11 Aug 2020 23:10:53 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                 | (b) (4)              | 11 Aug 2020 23:10:25 |
|                                                                                                                                                                                                                                                                                                               | System               | 11 Aug 2020 23:09:51 |

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**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:34:14**

[Condition](#)

| Audit                    | User                           | Time (GMT)           |
|--------------------------|--------------------------------|----------------------|
| User entered 'Cateracts' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:09:39 |

US3532002

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 2018' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:09:39 |

US3532002

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:09:39 |

US3532002

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:34:14**

[Condition ongoing at study entry](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:21:05 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 11 Aug 2020 23:21:05 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Etza Peters (b) (4) | 11 Aug 2020 23:21:05 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:09:39 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 11 Aug 2020 23:09:39 |



US3532002

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un Sep 2018' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:09:39 |

US3532002

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:34:14**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:09:39 |

US3532002

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2018' | System | 11 Aug 2020 23:09:39 |

US3532002

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2018' | System | 11 Aug 2020 23:09:39 |

US3532002

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Sep 2018' | System | 11 Aug 2020 23:09:39 |

US3532002

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2018' | System | 11 Aug 2020 23:09:39 |

US3532002

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:34:14

[Condition](#)

| Audit                                                                                                                                                                                                                                                                                                       | User                            | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\23.0.                                                                                                   | Coder Import (b) (4)<br>(b) (4) | 24 Oct 2020 23:50:41 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                                                                                                                                      | Coder Import (b) (4)<br>(b) (4) | 24 Oct 2020 23:50:41 |
| User closed query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.<br>' (Site from DM).             | (b) (4), (b) (6)                | 23 Oct 2020 08:42:13 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Bilateral cataract extraction - version MedDRA\23.0.                                                                                        | Coder Import (b) (4)<br>(b) (4) | 21 Oct 2020 10:16:34 |
| 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 10:16:34 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                               | System                          | 20 Oct 2020 16:47:28 |
| Query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.<br>' answered with 'Updated' (Site from DM). | Etza Peters (b) (4)<br>(b) (4)  | 20 Oct 2020 16:47:16 |
| Coding entries removed.                                                                                                                                                                                                                                                                                     | Etza Peters (b) (4)<br>(b) (4)  | 20 Oct 2020 16:47:10 |
| User entered 'Bilateral CATARACT SURGERIES' reason for change: Data Entry Error                                                                                                                                                                                                                             | Etza Peters (b) (4)<br>(b) (4)  | 20 Oct 2020 16:47:10 |
| User opened query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.<br>' (Site from DM).             | (b) (4), (b) (6)                | 29 Sep 2020 10:45:04 |

US3532002

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:34:14

[Condition](#)

| Audit                                                                                                                                                                                                      | User                            | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 23:13:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                               | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 23:13:20 |
| Data point term sent to Coder                                                                                                                                                                              | System                          | 11 Aug 2020 23:12:55 |
| User entered 'Cataract Surgery'                                                                                                                                                                            | Etza Peters (b) (4)<br>(b) (4)  | 11 Aug 2020 23:12:54 |



US3532002

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un Sep 2018' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:12:54 |

US3532002

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:12:54 |

US3532002

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:34:14

[Condition ongoing at study entry](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:21:12 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 11 Aug 2020 23:21:12 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Etza Peters (b) (4) | 11 Aug 2020 23:21:12 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:12:54 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 11 Aug 2020 23:12:54 |

US3532002

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un Sep 2018' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:12:54 |

US3532002

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:34:14**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:12:54 |

US3532002

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Sep 2018' | System | 11 Aug 2020 23:12:54 |

US3532002

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2018' | System | 11 Aug 2020 23:12:54 |

US3532002

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Sep 2018' | System | 11 Aug 2020 23:12:54 |



US3532002

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2018' | System | 11 Aug 2020 23:12:54 |

US3532002

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:34:14

Condition

| Audit                                                                                                                                                                                                      | User                 | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.                     | Coder Import (b) (4) | 11 Aug 2020 23:19:15 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                               | Coder Import (b) (4) | 11 Aug 2020 23:19:15 |
| Data point term sent to Coder                                                                                                                                                                              | System               | 11 Aug 2020 23:18:04 |
| Coding entries removed.                                                                                                                                                                                    | Etza Peters (b) (4)  | 11 Aug 2020 23:17:16 |
| User entered 'Hypothyroidism' reason for change: Data Entry Error                                                                                                                                          | Etza Peters (b) (4)  | 11 Aug 2020 23:17:16 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Aug 2020 23:13:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                               | Coder Import (b) (4) | 11 Aug 2020 23:13:20 |
| Data point term sent to Coder                                                                                                                                                                              | System               | 11 Aug 2020 23:11:54 |
| User entered 'Cataract Surgery'                                                                                                                                                                            | Etza Peters (b) (4)  | 11 Aug 2020 23:11:18 |

US3532002

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                                                  | User                | Time (GMT)           |
|--------------------------------------------------------|---------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Etza Peters (b) (4) | 01 Sep 2020 18:57:45 |
| User entered 'un Sep 2018'                             | Etza Peters (b) (4) | 11 Aug 2020 23:11:18 |

US3532002

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit                                                                                                                                   | User                                      | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|----------------------|
| User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System). | System                                    | 01 Sep 2020 18:57:45 |
| User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System). | System                                    | 01 Sep 2020 18:57:34 |
| User entered '1' reason for change: Data Entry Error                                                                                    | Etza Peters (b) (4)                       | 01 Sep 2020 18:57:34 |
| User entered '0'                                                                                                                        | (b) (4)<br>Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:11:18 |

US3532002

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:34:14

[Condition ongoing at study entry](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:17:16 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 11 Aug 2020 23:17:16 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | Etza Peters (b) (4) | 11 Aug 2020 23:17:16 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:11:18 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 11 Aug 2020 23:11:18 |

US3532002

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                                                  | User                | Time (GMT)           |
|--------------------------------------------------------|---------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Etza Peters (b) (4) | 11 Aug 2020 23:17:16 |
| User entered 'un Sep 2018'                             | Etza Peters (b) (4) | 11 Aug 2020 23:11:18 |

US3532002

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:34:14**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:11:18 |

US3532002

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered empty.     | System | 01 Sep 2020 18:57:45 |
| User entered 'Sep 2018' | System | 11 Aug 2020 23:11:18 |



US3532002

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Sep 2020 18:57:45 |
| User entered '2018' | System | 11 Aug 2020 23:11:18 |

US3532002

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered empty.     | System | 11 Aug 2020 23:17:16 |
| User entered 'Sep 2018' | System | 11 Aug 2020 23:11:18 |

US3532002

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 23:17:16 |
| User entered '2018' | System | 11 Aug 2020 23:11:18 |

US3532002

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:34:14

[Condition](#)

| Audit                                                                                                                                                                                                                                                                                                             | User                            | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 22 Sep 2020 23:43:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                                                                                                                           | Coder Import (b) (4)<br>(b) (4) | 22 Sep 2020 23:43:47 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                     | System                          | 22 Sep 2020 22:12:29 |
| Coding entries removed.                                                                                                                                                                                                                                                                                           | Etza Peters (b) (4)<br>(b) (4)  | 22 Sep 2020 22:11:42 |
| User entered 'Degenerative Disk Disease of Back' reason for change: Data Entry Error                                                                                                                                                                                                                              | Etza Peters (b) (4)<br>(b) (4)  | 22 Sep 2020 22:11:42 |
| 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: Back pain - version MedDRA\\23.0.                                                   | Coder Import (b) (4)<br>(b) (4) | 01 Sep 2020 18:58:51 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                                                                                                      | Coder Import (b) (4)<br>(b) (4) | 01 Sep 2020 18:58:51 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                     | System                          | 01 Sep 2020 18:58:12 |
| User entered 'Back pain'                                                                                                                                                                                                                                                                                          | Etza Peters (b) (4)<br>(b) (4)  | 01 Sep 2020 18:57:12 |

US3532002

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                                                             | User                           | Time (GMT)           |
|-------------------------------------------------------------------|--------------------------------|----------------------|
| User entered 'UN Nov 2019' reason for change:<br>Data Entry Error | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 22:11:42 |
| User entered empty.                                               | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:57:12 |

US3532002

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:34:14

[Start date completely unknown](#)

| Audit                                                                                                                                   | User                | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System). | System              | 22 Sep 2020 22:11:50 |
| User entered '0' reason for change: Data Entry Error                                                                                    | Etza Peters (b) (4) | 22 Sep 2020 22:11:50 |
| User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System). | (b) (4)             | 22 Sep 2020 22:11:42 |
| User entered '1'                                                                                                                        | Etza Peters (b) (4) | 01 Sep 2020 18:57:12 |

US3532002

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:34:14**

[Condition ongoing at study entry](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:57:12 |

US3532002

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:57:12 |



US3532002

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:34:14**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:57:12 |

US3532002

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Nov 2019' | System | 22 Sep 2020 22:11:42 |
| User entered empty.     | System | 01 Sep 2020 18:57:12 |

US3532002

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2019' | System | 22 Sep 2020 22:11:42 |
| User entered empty. | System | 01 Sep 2020 18:57:12 |

US3532002

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Sep 2020 18:57:12 |

US3532002

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Sep 2020 18:57:12 |

US3532002

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:34:14

[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: Cartilage injury, LLT: Cartilage tear in knee - version MedDRA\\23.0. | Coder Import (b) (4) | 26 Oct 2020 19:25:02 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                             | Coder Import (b) (4) | 26 Oct 2020 19:25:02 |
| Data point term sent to Coder                                                                                                                                                                                            | System               | 26 Oct 2020 18:21:24 |
| User entered 'Torn Cartilage in Right Knee'                                                                                                                                                                              | Etza Peters (b) (4)  | 26 Oct 2020 18:21:18 |

US3532002

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 26 Oct 2020 18:21:18 |

US3532002

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '1' | Etza Peters (b) (4)<br>(b) (4) | 26 Oct 2020 18:21:18 |



US3532002

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 09:34:14**

[Condition ongoing at study entry](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 26 Oct 2020 18:21:18 |

US3532002

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 1984' | Etza Peters (b) (4)<br>(b) (4) | 26 Oct 2020 18:21:18 |

US3532002

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 09:34:14**

[Stop date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 26 Oct 2020 18:21:18 |

US3532002

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 18:21:18 |

US3532002

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 18:21:18 |

US3532002

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1984' | System | 26 Oct 2020 18:21:18 |

US3532002

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1984' | System | 26 Oct 2020 18:21:18 |

US3532002

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

[Were vital signs assessed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:46:16 |



US3532002

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '11 Aug 2020' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:46:16 |

US3532002

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| User entered '15:11' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:46:16 |

US3532002

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 15:11' | System | 11 Aug 2020 22:46:16 |

US3532002

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                     | User                | Time (GMT)           |
|---------------------------|---------------------|----------------------|
| User entered '174' cm     | Etza Peters (b) (4) | 11 Aug 2020 22:46:16 |
| DataPoint set to visible. | (b) (4)<br>System   | 11 Aug 2020 22:06:44 |

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:14

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

| Audit                     | User                | Time (GMT)           |
|---------------------------|---------------------|----------------------|
| User entered '85.5' kg    | Etza Peters (b) (4) | 11 Aug 2020 22:46:16 |
| DataPoint set to visible. | (b) (4)<br>System   | 11 Aug 2020 22:06:44 |

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:14

BMI (xxx.x)

| Audit                                      | User   | Time (GMT)           |
|--------------------------------------------|--------|----------------------|
| Amendment Manager: User entered '28.24019' | System | 16 Sep 2020 23:52:16 |
| User entered '28.2'                        | System | 11 Aug 2020 22:46:16 |
| DataPoint set to visible.                  | System | 11 Aug 2020 22:06:44 |

US3532002

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

[BMI units](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered 'kg/m2'      | System | 11 Aug 2020 22:46:16 |
| DataPoint set to visible. | System | 11 Aug 2020 22:06:44 |

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:14

Temperature (xxx.x)

| Audit                                                                                                                                                                                                                                                    | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).          | (b) (4), (b) (6)       | 26 Aug 2020 09:27:47 |
| Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' answered with 'DONE' (Site from DM). | Laila Hussaini (b) (4) | 26 Aug 2020 01:38:53 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                                                                              | Laila Hussaini (b) (4) | 26 Aug 2020 01:38:48 |
| User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).          | (b) (4), (b) (6)       | 24 Aug 2020 09:36:33 |
| User entered '98.9' F                                                                                                                                                                                                                                    | Etza Peters (b) (4)    | 11 Aug 2020 22:46:16 |



US3532002

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:14

[Route of measurement](#)

| Audit                                                  | User                   | Time (GMT)           |
|--------------------------------------------------------|------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Laila Hussaini (b) (4) | 26 Aug 2020 01:38:48 |
| User entered 'Oral (Oral)'                             | Etza Peters (b) (4)    | 11 Aug 2020 22:46:16 |

US3532002

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

[If Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:46:16 |

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:14

[Pulse \(xxx\)](#)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Laila Hussaini (b) (4) | 26 Aug 2020 01:38:48 |
| User entered '80'                                                           | Etza Peters (b) (4)    | 11 Aug 2020 22:46:16 |

US3532002

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 11 Aug 2020 22:46:16 |

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Laila Hussaini (b) (4) | 26 Aug 2020 01:38:48 |
| User entered '12'                                                           | Etza Peters (b) (4)    | 11 Aug 2020 22:46:16 |

US3532002

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 11 Aug 2020 22:46:16 |

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Laila Hussaini (b) (4) | 26 Aug 2020 01:38:48 |
| User entered '139'                                                          | Etza Peters (b) (4)    | 11 Aug 2020 22:46:16 |

US3532002

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 11 Aug 2020 22:46:16 |



US3532002

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Laila Hussaini (b) (4) | 26 Aug 2020 01:38:48 |
| User entered '89'                                                           | Etza Peters (b) (4)    | 11 Aug 2020 22:46:16 |

US3532002

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 11 Aug 2020 22:46:16 |

US3532002

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:34:14**

[Was the physical examination performed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:43:30 |

US3532002

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:34:14**

[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)    | 11 Sep 2020 18:36:34 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System              | 08 Sep 2020 12:21:11 |
| User entered '11 Aug 2020'                                                                                                               | Etza Peters (b) (4) | 11 Aug 2020 22:43:30 |

US3532002

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |

US3532002

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:14

**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)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:14

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

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |



US3532002

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:14

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

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |

US3532002

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:34:14**

**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)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |

US3532002

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |

US3532002

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                 | User                | Time (GMT)           |
|-----------------------|---------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4) | 11 Aug 2020 23:27:29 |
|                       | (b) (4)             |                      |

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:14

**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)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |

US3532002

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:34:14**

**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)' | Etza Peters (b) (4) | 11 Aug 2020 23:27:29 |

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:14

[Other](#)

| Audit                  | User                | Time (GMT)           |
|------------------------|---------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4) | 11 Aug 2020 23:27:29 |
|                        | (b) (4)             |                      |



US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:14

[Specify](#)

| Audit                                                     | User                | Time (GMT)           |
|-----------------------------------------------------------|---------------------|----------------------|
| User entered 'Engineer-performs site inspections 3X/week' | Etza Peters (b) (4) | 11 Aug 2020 23:27:29 |

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:14

No Risk Identified

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |

US3532002

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:14

**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' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:14

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

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:14

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' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |

US3532002

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:34:14**

**Resides in a single family home** (i.e., detached housing)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '1' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:14

[Other](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |



US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:14

[Specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:27:29 |

US3532002

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:34:14

[Was this visit performed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:35:09 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '11 Aug 2020' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:35:09 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 19:35:09 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:34:14**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 11 Aug 2020 19:35:09 |

US3532002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:14

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

| Audit                      | User                                            | Time (GMT)           |
|----------------------------|-------------------------------------------------|----------------------|
| User entered '11 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 11 Aug 2020 20:44:29 |

US3532002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:14

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 03:40:03 |
| Amendment Manager: Data point set to conformant.                                                           | System                                         | 21 Aug 2020 03:40:03 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).                    | System                                         | 11 Aug 2020 20:44:29 |
| User entered '143706' (non-conformant).                                                                    | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 11 Aug 2020 20:44:29 |

US3532002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:14

[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><div></div> | 11 Aug 2020 20:44:29 |



US3532002

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 21:26:40 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 21:26:40 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 21:26:40 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:34:14**

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 21:26:40 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:34:14**

[Liver Disease](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 21:26:40 |

US3532002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                        | User                | Time (GMT)           |
|----------------------------------------------|---------------------|----------------------|
| User entered 'No (N)'                        | Etza Peters (b) (4) | 24 Sep 2020 18:08:02 |
| Amendment Manager: DataPoint set to visible. | (b) (4)             | 19 Sep 2020 10:17:54 |
| Amendment Manager inserted this DataPoint.   | System              | 19 Sep 2020 06:35:35 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:14

Height

| Audit                                                                                                                                                                   | User                   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).          | (b) (4), (b) (6)       | 26 Aug 2020 10:17:55 |
| Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'DONE' (Site from DM). | Laila Hussaini (b) (4) | 26 Aug 2020 01:40:28 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                             | Laila Hussaini (b) (4) | 26 Aug 2020 01:40:15 |
| User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).          | (b) (4), (b) (6)       | 19 Aug 2020 01:53:01 |
| User entered empty.                                                                                                                                                     | Etza Peters (b) (4)    | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:14

Weight

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Laila Hussaini (b) (4) | 26 Aug 2020 01:40:22 |
| User entered empty.                                                         | Etza Peters (b) (4)    | 11 Aug 2020 22:26:58 |



US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:14

Height

| Audit                                                                                                                                                                   | User                   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).          | (b) (4), (b) (6)       | 26 Aug 2020 10:17:55 |
| Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'DONE' (Site from DM). | Laila Hussaini (b) (4) | 26 Aug 2020 01:40:28 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                             | Laila Hussaini (b) (4) | 26 Aug 2020 01:40:15 |
| User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).          | (b) (4), (b) (6)       | 19 Aug 2020 01:53:01 |
| User entered empty.                                                                                                                                                     | Etza Peters (b) (4)    | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:14

Weight

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Laila Hussaini (b) (4) | 26 Aug 2020 01:40:22 |
| User entered empty.                                                         | Etza Peters (b) (4)    | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:14

[Timepoint](#)

| Audit                                            | User                           | Time (GMT)           |
|--------------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:26:58 |

US3532002

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:34:14**

[Were vital signs assessed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:14

Date of assessment (*dd MMM yyyy*)

| Audit                                                                        | User                           | Time (GMT)           |
|------------------------------------------------------------------------------|--------------------------------|----------------------|
| User closed query 'Data is required. Please provide.'<br>(Site from System). | System                         | 11 Aug 2020 23:44:20 |
| User entered '11 Aug 2020' reason for change: Data<br>Entry Error            | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:44:20 |
| User opened query 'Data is required. Please provide.'<br>(Site from System). | System                         | 11 Aug 2020 22:26:58 |
| User entered empty.                                                          | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                        | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 23:44:20 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                     | 11 Aug 2020 23:44:20 |
| User entered '15:11' reason for change: Data Entry Error                                     | Etza Peters (b) (4) | 11 Aug 2020 23:44:20 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 22:26:58 |
| User entered empty.                                                                          | Etza Peters (b) (4) | 11 Aug 2020 22:26:58 |

US3532002

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 15:11' | System | 11 Aug 2020 23:44:20 |
| User entered empty.              | System | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:14

Temperature (xxx.x)

| Audit                                                                                        | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 23:44:20 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                     | 11 Aug 2020 23:44:20 |
| User entered '98.9' F reason for change: Data Entry Error                                    | Etza Peters (b) (4) | 11 Aug 2020 23:44:20 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 22:26:58 |
| User entered empty.                                                                          | Etza Peters (b) (4) | 11 Aug 2020 22:26:58 |



US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:14

[Route of measurement](#)

| Audit                                                                     | User                | Time (GMT)           |
|---------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System). | System              | 11 Aug 2020 23:45:11 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error            | Etza Peters (b) (4) | 11 Aug 2020 23:45:11 |
| User opened query 'Data is required. Please provide.' (Site from System). | System              | 11 Aug 2020 22:26:58 |
| User entered empty.                                                       | Etza Peters (b) (4) | 11 Aug 2020 22:26:58 |

US3532002

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:34:14**

[If Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:14

[Pulse \(xxx\)](#)

| Audit                                                                                        | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 23:45:11 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                     | 11 Aug 2020 23:45:11 |
| User entered '80' reason for change: Data Entry Error                                        | Etza Peters (b) (4) | 11 Aug 2020 23:45:11 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 22:26:58 |
| User entered empty.                                                                          | Etza Peters (b) (4) | 11 Aug 2020 22:26:58 |

US3532002

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:34:14**

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'bpm'  | System | 11 Aug 2020 23:45:11 |
| User entered empty. | System | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                        | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 23:45:11 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                     | 11 Aug 2020 23:45:11 |
| User entered '12' reason for change: Data Entry Error                                        | Etza Peters (b) (4) | 11 Aug 2020 23:45:11 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 22:26:58 |
| User entered empty.                                                                          | Etza Peters (b) (4) | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:14

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 11 Aug 2020 23:45:11 |
| User entered empty.        | System | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                        | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 23:45:11 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                     | 11 Aug 2020 23:45:11 |
| User entered '139' reason for change: Data Entry Error                                       | Etza Peters (b) (4) | 11 Aug 2020 23:45:11 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 22:26:58 |
| User entered empty.                                                                          | Etza Peters (b) (4) | 11 Aug 2020 22:26:58 |

US3532002

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:34:14**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 11 Aug 2020 23:45:11 |
| User entered empty. | System | 11 Aug 2020 22:26:58 |



US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                        | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 23:45:11 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                     | 11 Aug 2020 23:45:11 |
| User entered '89' reason for change: Data Entry Error                                        | Etza Peters (b) (4) | 11 Aug 2020 23:45:11 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 22:26:58 |
| User entered empty.                                                                          | Etza Peters (b) (4) | 11 Aug 2020 22:26:58 |

US3532002

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:34:14**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 11 Aug 2020 23:45:11 |
| User entered empty. | System | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:14

Height

| Audit                                                                                                                                                                   | User                   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).          | (b) (4), (b) (6)       | 26 Aug 2020 10:17:55 |
| Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'DONE' (Site from DM). | Laila Hussaini (b) (4) | 26 Aug 2020 01:40:28 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                             | Laila Hussaini (b) (4) | 26 Aug 2020 01:40:15 |
| User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).          | (b) (4), (b) (6)       | 19 Aug 2020 01:53:01 |
| User entered empty.                                                                                                                                                     | Etza Peters (b) (4)    | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:14

Weight

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Laila Hussaini (b) (4) | 26 Aug 2020 01:40:22 |
| User entered empty.                                                         | Etza Peters (b) (4)    | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

[Timepoint](#)

| Audit                                              | User                           | Time (GMT)           |
|----------------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

[Were vital signs assessed?](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:45:48 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 11 Aug 2020 23:45:48 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | Etza Peters (b) (4) | 11 Aug 2020 23:45:48 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 22:26:58 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

Date of assessment (*dd MMM yyyy*)

| Audit                                                          | User                | Time (GMT)           |
|----------------------------------------------------------------|---------------------|----------------------|
| User entered '11 Aug 2020' reason for change: Data Entry Error | Etza Peters (b) (4) | 11 Aug 2020 23:45:48 |
| User entered empty.                                            | Etza Peters (b) (4) | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                           | User                | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed 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).                                        | (b) (4), (b) (6)    | 19 Aug 2020 01:49:43 |
| User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).                                                                                  | System              | 12 Aug 2020 12:39:57 |
| User entered '17:51' reason for change: Data Entry Error                                                                                                                                        | Etza Peters (b) (4) | 12 Aug 2020 12:39:57 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol 30 minutes or greater' (Site from System). | Etza Peters (b) (4) | 11 Aug 2020 23:47:03 |
| User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).                                                                                  | System              | 11 Aug 2020 23:45:48 |
| 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              | 11 Aug 2020 23:45:48 |
| User entered '14:51' reason for change: Data Entry Error                                                                                                                                        | Etza Peters (b) (4) | 11 Aug 2020 23:45:48 |
| User entered empty.                                                                                                                                                                             | Etza Peters (b) (4) | 11 Aug 2020 22:26:58 |



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**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 17:51' | System | 12 Aug 2020 12:39:57 |
| User entered '11 Aug 2020 14:51' | System | 11 Aug 2020 23:45:48 |
| User entered empty.              | System | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

Temperature (xxx.x)

| Audit                                                                                        | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System).      | System              | 12 Aug 2020 12:35:51 |
| User entered '98.4' F reason for change: Data Entry Error                                    | Etza Peters (b) (4) | 12 Aug 2020 12:35:51 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).      | System              | 11 Aug 2020 23:46:22 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 23:46:22 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                     | 11 Aug 2020 23:46:22 |
| User entered '98.4' (non-conformant).                                                        | Etza Peters (b) (4) | 11 Aug 2020 23:46:22 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 23:45:48 |
| User entered empty.                                                                          | Etza Peters (b) (4) | 11 Aug 2020 22:26:58 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

[Route of measurement](#)

| Audit                                                                     | User                | Time (GMT)           |
|---------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System). | System              | 11 Aug 2020 23:46:22 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error            | Etza Peters (b) (4) | 11 Aug 2020 23:46:22 |
| User opened query 'Data is required. Please provide.' (Site from System). | System              | 11 Aug 2020 23:45:48 |
| User entered empty.                                                       | Etza Peters (b) (4) | 11 Aug 2020 22:26:58 |

US3532002

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:34:14**

[If Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

[Pulse \(xxx\)](#)

| Audit                                                                                        | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 23:46:22 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                     | 11 Aug 2020 23:46:22 |
| User entered '71' reason for change: Data Entry Error                                        | Etza Peters (b) (4) | 11 Aug 2020 23:46:22 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 23:45:48 |
| User entered empty.                                                                          | Etza Peters (b) (4) | 11 Aug 2020 22:26:58 |

US3532002

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:34:14**

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'bpm'  | System | 11 Aug 2020 23:46:22 |
| User entered empty. | System | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                        | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 23:46:22 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                     | 11 Aug 2020 23:46:22 |
| User entered '12' reason for change: Data Entry Error                                        | Etza Peters (b) (4) | 11 Aug 2020 23:46:22 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 23:45:48 |
| User entered empty.                                                                          | Etza Peters (b) (4) | 11 Aug 2020 22:26:58 |

US3532002

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:34:14**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 11 Aug 2020 23:46:22 |
| User entered empty.        | System | 11 Aug 2020 22:26:58 |



US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

Systolic Blood Pressure (xxx)

| Audit                                                                                                                                                                                                                                                            | User                           | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User closed query 'Re-Query : Per query response, please indicate if CS/NCS and report as AE, if appropriate. Thank you.' (Site from DM).                                                                                                                        | (b) (4), (b) (6)               | 13 Aug 2020 14:12:08 |
| Query 'Re-Query : Per query response, please indicate if CS/NCS and report as AE, if appropriate. Thank you.' answered with 'NCS, Not related: Due to underlying hypertension and due for evening meds' (Site from DM).                                          | Etza Peters (b) (4)<br>(b) (4) | 12 Aug 2020 12:42:07 |
| User opened query 'Re-Query : Per query response, please indicate if CS/NCS and report as AE, if appropriate. Thank you.' (Site from DM).                                                                                                                        | (b) (4), (b) (6)               | 12 Aug 2020 11:01:34 |
| User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).                                                              | (b) (4), (b) (6)               | 12 Aug 2020 11:00:50 |
| Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Subject due to take his evening blood pressure medicaion' (Site from System). | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:48:24 |
| User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).                                                              | System                         | 11 Aug 2020 23:46:22 |
| User closed query 'Data is required. Please provide.' (Site from System).                                                                                                                                                                                        | System                         | 11 Aug 2020 23:46:22 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System).                                                                                                                                                                     |                                | 11 Aug 2020 23:46:22 |
| User entered '165' reason for change: Data Entry Error                                                                                                                                                                                                           | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:46:22 |
| User opened query 'Data is required. Please provide.' (Site from System).                                                                                                                                                                                        | System                         | 11 Aug 2020 23:45:48 |
| User entered empty.                                                                                                                                                                                                                                              | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:26:58 |

US3532002

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:34:14**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 11 Aug 2020 23:46:22 |
| User entered empty. | System | 11 Aug 2020 22:26:58 |

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                        | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 23:46:22 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                     | 11 Aug 2020 23:46:22 |
| User entered '95' reason for change: Data Entry Error                                        | Etza Peters (b) (4) | 11 Aug 2020 23:46:22 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System              | 11 Aug 2020 23:45:48 |
| User entered empty.                                                                          | Etza Peters (b) (4) | 11 Aug 2020 22:26:58 |

US3532002

**Folder: Visit 1 Day 1**

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

**Generated On: 26 Nov 2020 09:34:14**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 11 Aug 2020 23:46:22 |
| User entered empty. | System | 11 Aug 2020 22:26:58 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:34:14**

[Was the physical examination performed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:11:05 |

US3532002

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:14

Date of examination (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '11 Aug 2020' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:11:05 |

US3532002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:14

[Was study treatment given?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:10:10 |

US3532002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:14

If No, reason not given

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:10:10 |



US3532002

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:10:10 |

US3532002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:14

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:34:14**

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '11 Aug 2020' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:10:10 |

US3532002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:14

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| User entered '17:21' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:34:14**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 17:21' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:14

[Which arm was used to give treatment?](#)

| Audit                              | User                           | Time (GMT)           |
|------------------------------------|--------------------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:34:14**

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:34:14**

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 11 Aug 2020 22:10:10 |



US3532002

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:34:14**

[Was the sample collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:10:40 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '11 Aug 2020' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:10:40 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:34:14**

[Collection time \(00:00-23:59\)](#)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| User entered '16:49' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:10:40 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 16:49' | System | 11 Aug 2020 22:10:40 |

US3532002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:34:14

Collection date (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '11 Aug 2020' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:08:48 |

US3532002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:14

[Lab Test](#)

| Audit                                                        | User                | Time (GMT)           |
|--------------------------------------------------------------|---------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Etza Peters (b) (4) | 11 Aug 2020 22:08:48 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Was the sample collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:08:48 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Collection time \(00:00 - 23:59\)](#)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| User entered '16:35' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:08:48 |



US3532002

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 16:35' | System | 11 Aug 2020 22:08:48 |

US3532002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:14

[Lab Test](#)

| Audit                                                        | User                | Time (GMT)           |
|--------------------------------------------------------------|---------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Etza Peters (b) (4) | 11 Aug 2020 22:08:48 |

US3532002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:14

[Was the sample collected?](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 22:08:57 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 11 Aug 2020 22:08:57 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Etza Peters (b) (4) | 11 Aug 2020 22:08:57 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 22:08:48 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 11 Aug 2020 22:08:48 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Collection time \(00:00 - 23:59\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:08:48 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 22:08:48 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 22:10:48 |

US3532002

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 22:10:48 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 11 Aug 2020 22:10:10 |



US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:17:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'eb4a6fdb-d1e8-4261-9f6b-cad254d705e4' | System | 11 Aug 2020 22:17:26 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 11 Aug 2020 22:17:26 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:17:13', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'eb4a6fdb-d1e8-4261-9f6b-cad254d705e4' | System | 11 Aug 2020 22:17:26 |
| User entered '98.4'                                                                                                                                                                                                                        | System | 11 Aug 2020 22:17:26 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:17:16', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'eb4a6fdb-d1e8-4261-9f6b-cad254d705e4' | System | 11 Aug 2020 22:17:26 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 11 Aug 2020 22:17:26 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:17:23', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'eb4a6fdb-d1e8-4261-9f6b-cad254d705e4' | System | 11 Aug 2020 22:17:26 |
| User entered '11 Aug 2020 18:17'                                                                                                                                                                                                           | System | 11 Aug 2020 22:17:26 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 17:41' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 20:11' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 1, after vaccination (at home)' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:20:07', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a0d5830c-edf9-460e-9a92-ccacbeefc355' | System | 12 Aug 2020 01:29:04 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 12 Aug 2020 01:29:04 |



US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:28:47', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a0d5830c-edf9-460e-9a92-ccacbeefc355' | System | 12 Aug 2020 01:29:04 |
| User entered '97.6'                                                                                                                                                                                                                        | System | 12 Aug 2020 01:29:04 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:28:53', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a0d5830c-edf9-460e-9a92-ccacbeefc355' | System | 12 Aug 2020 01:29:04 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 12 Aug 2020 01:29:04 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:29:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a0d5830c-edf9-460e-9a92-ccacbeefc355' | System | 12 Aug 2020 01:29:04 |
| User entered '11 Aug 2020 21:29'                                                                                                                                                                                                           | System | 12 Aug 2020 01:29:04 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 21:06' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 2' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:34:14

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:18:27', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1c181a4-fedd-499f-83db-04ee64f657c5' | System | 12 Aug 2020 16:18:49 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 12 Aug 2020 16:18:49 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:34:14

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:18:34', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1c181a4-fedd-499f-83db-04ee64f657c5' | System | 12 Aug 2020 16:18:49 |
| User entered '97.2'                                                                                                                                                                                                                        | System | 12 Aug 2020 16:18:49 |



US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:18:39', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1c181a4-fedd-499f-83db-04ee64f657c5' | System | 12 Aug 2020 16:18:49 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 12 Aug 2020 16:18:49 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:18:45', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1c181a4-fedd-499f-83db-04ee64f657c5' | System | 12 Aug 2020 16:18:49 |
| User entered '12 Aug 2020 12:18'                                                                                                                                                                                                           | System | 12 Aug 2020 16:18:49 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 3' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:34:14

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:34:58', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'beeadde3-3a28-45ab-b2a2-4ee9c6cd24f3' | System | 13 Aug 2020 20:35:34 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 13 Aug 2020 20:35:34 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:34:14

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:35:20', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'beeadde3-3a28-45ab-b2a2-4ee9c6cd24f3' | System | 13 Aug 2020 20:35:34 |
| User entered '97.8'                                                                                                                                                                                                                        | System | 13 Aug 2020 20:35:34 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:35:24', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'beeadde3-3a28-45ab-b2a2-4ee9c6cd24f3' | System | 13 Aug 2020 20:35:34 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 13 Aug 2020 20:35:34 |



US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:35:31', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'beeadde3-3a28-45ab-b2a2-4ee9c6cd24f3' | System | 13 Aug 2020 20:35:34 |
| User entered '13 Aug 2020 16:35'                                                                                                                                                                                                           | System | 13 Aug 2020 20:35:34 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 4' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:34:14

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:20:57', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'cf1107e1-d38d-4659-8bf9-9d070c456b56' | System | 14 Aug 2020 22:21:19 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 14 Aug 2020 22:21:19 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:34:14

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:21:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'cf1107e1-d38d-4659-8bf9-9d070c456b56' | System | 14 Aug 2020 22:21:19 |
| User entered '98.0'                                                                                                                                                                                                                        | System | 14 Aug 2020 22:21:19 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:21:06', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'cf1107e1-d38d-4659-8bf9-9d070c456b56' | System | 14 Aug 2020 22:21:19 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 14 Aug 2020 22:21:19 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:21:17', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'cf1107e1-d38d-4659-8bf9-9d070c456b56' | System | 14 Aug 2020 22:21:19 |
| User entered '14 Aug 2020 18:21'                                                                                                                                                                                                           | System | 14 Aug 2020 22:21:19 |



US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '15 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 5' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:09:54', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f993e0ba-0525-4aa6-8678-c85ee3d9fbc2' | System | 15 Aug 2020 22:10:49 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 15 Aug 2020 22:10:49 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:34:14

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:10:36', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f993e0ba-0525-4aa6-8678-c85ee3d9fbc2' | System | 15 Aug 2020 22:10:49 |
| User entered '98.1'                                                                                                                                                                                                                        | System | 15 Aug 2020 22:10:49 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:10:40', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f993e0ba-0525-4aa6-8678-c85ee3d9fbc2' | System | 15 Aug 2020 22:10:49 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 15 Aug 2020 22:10:49 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:10:46', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f993e0ba-0525-4aa6-8678-c85ee3d9fbc2' | System | 15 Aug 2020 22:10:49 |
| User entered '15 Aug 2020 18:10'                                                                                                                                                                                                           | System | 15 Aug 2020 22:10:49 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '15 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |



US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 6' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:34:14

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:41:01', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e285af8-30a5-475d-a292-0182b1bca11d' | System | 16 Aug 2020 23:41:22 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 16 Aug 2020 23:41:22 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:34:14

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:41:09', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e285af8-30a5-475d-a292-0182b1bca11d' | System | 16 Aug 2020 23:41:22 |
| User entered '98.1'                                                                                                                                                                                                                        | System | 16 Aug 2020 23:41:22 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:41:13', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e285af8-30a5-475d-a292-0182b1bca11d' | System | 16 Aug 2020 23:41:22 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 16 Aug 2020 23:41:22 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:41:19', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e285af8-30a5-475d-a292-0182b1bca11d' | System | 16 Aug 2020 23:41:22 |
| User entered '16 Aug 2020 19:41'                                                                                                                                                                                                           | System | 16 Aug 2020 23:41:22 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |



US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 7' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:34:14

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:32:08', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a4fa5a3d-7484-4575-b9ea-b1fde0c6c63d' | System | 17 Aug 2020 21:32:25 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 17 Aug 2020 21:32:25 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:32:14', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a4fa5a3d-7484-4575-b9ea-b1fde0c6c63d' | System | 17 Aug 2020 21:32:25 |
| User entered '97.8'                                                                                                                                                                                                                        | System | 17 Aug 2020 21:32:25 |

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:32:18', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a4fa5a3d-7484-4575-b9ea-b1fde0c6c63d' | System | 17 Aug 2020 21:32:25 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 17 Aug 2020 21:32:25 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:32:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a4fa5a3d-7484-4575-b9ea-b1fde0c6c63d' | System | 17 Aug 2020 21:32:25 |
| User entered '17 Aug 2020 17:32'                                                                                                                                                                                                           | System | 17 Aug 2020 21:32:25 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 11 Aug 2020 22:10:10 |



US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-11T18:17:52', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '88a3e73c-114f-4570-a49c-f1c65871d601' | System | 11 Aug 2020 22:18:23 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 11 Aug 2020 22:18:23 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:17:56', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '88a3e73c-114f-4570-a49c-f1c65871d601' | System | 11 Aug 2020 22:18:23 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 11 Aug 2020 22:18:23 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:18:06', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '88a3e73c-114f-4570-a49c-f1c65871d601' | System | 11 Aug 2020 22:18:23 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 11 Aug 2020 22:18:23 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-11T18:18:13', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '88a3e73c-114f-4570-a49c-f1c65871d601' | System | 11 Aug 2020 22:18:23 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 11 Aug 2020 22:18:23 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:18:20', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '88a3e73c-114f-4570-a49c-f1c65871d601' | System | 11 Aug 2020 22:18:23 |
| User entered '11 Aug 2020 18:18'                                                                                                                                                                                                           | System | 11 Aug 2020 22:18:23 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 17:41' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 20:11' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 1, after vaccination (at home)' | System | 11 Aug 2020 22:10:10 |



US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-11T21:29:24', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5acc9fa2-4d40-4293-a15d-6b4a77c482a8' | System | 12 Aug 2020 01:32:40 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 12 Aug 2020 01:32:40 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:29:28', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5acc9fa2-4d40-4293-a15d-6b4a77c482a8' | System | 12 Aug 2020 01:32:40 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 12 Aug 2020 01:32:40 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:29:33', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5acc9fa2-4d40-4293-a15d-6b4a77c482a8' | System | 12 Aug 2020 01:32:40 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 12 Aug 2020 01:32:40 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

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

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

| Audit                                                                                                                                                                                                                                      | User                   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Comment added 'Per conversation with subject he believed the measurements were in cm not mm and therefore entered 2. The correct recording should be 20 mm.'                                                                               | Laila Hussaini (b) (4) | 14 Aug 2020 01:33:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:32:11', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5acc9fa2-4d40-4293-a15d-6b4a77c482a8' | System                 | 12 Aug 2020 01:32:40 |
| User entered '2'                                                                                                                                                                                                                           | System                 | 12 Aug 2020 01:32:40 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-11T21:32:25', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5acc9fa2-4d40-4293-a15d-6b4a77c482a8' | System | 12 Aug 2020 01:32:40 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 12 Aug 2020 01:32:40 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:32:37', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5acc9fa2-4d40-4293-a15d-6b4a77c482a8' | System | 12 Aug 2020 01:32:40 |
| User entered '11 Aug 2020 21:32'                                                                                                                                                                                                           | System | 12 Aug 2020 01:32:40 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 21:06' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |



US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 2' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-12T12:19:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '860ec768-d10c-4a46-88e1-064bfa496b50' | System | 12 Aug 2020 16:20:57 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 12 Aug 2020 16:20:57 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:34:14

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:19:09', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '860ec768-d10c-4a46-88e1-064bfa496b50' | System | 12 Aug 2020 16:20:57 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 12 Aug 2020 16:20:57 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:19:12', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '860ec768-d10c-4a46-88e1-064bfa496b50' | System | 12 Aug 2020 16:20:57 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 12 Aug 2020 16:20:57 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:34:14

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

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:20:29', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '860ec768-d10c-4a46-88e1-064bfa496b50' | System | 12 Aug 2020 16:20:57 |
| User entered '30'                                                                                                                                                                                                                          | System | 12 Aug 2020 16:20:57 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-12T12:20:39', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '860ec768-d10c-4a46-88e1-064bfa496b50' | System | 12 Aug 2020 16:20:57 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 12 Aug 2020 16:20:57 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:20:55', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '860ec768-d10c-4a46-88e1-064bfa496b50' | System | 12 Aug 2020 16:20:57 |
| User entered '12 Aug 2020 12:20'                                                                                                                                                                                                           | System | 12 Aug 2020 16:20:57 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |



US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 3' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-13T16:35:42', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e83b742f-6575-4958-93bf-584276e120c6' | System | 13 Aug 2020 20:36:23 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 13 Aug 2020 20:36:23 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:34:14

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:35:46', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e83b742f-6575-4958-93bf-584276e120c6' | System | 13 Aug 2020 20:36:23 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 13 Aug 2020 20:36:23 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:35:49', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e83b742f-6575-4958-93bf-584276e120c6' | System | 13 Aug 2020 20:36:23 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 13 Aug 2020 20:36:23 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e83b742f-6575-4958-93bf-584276e120c6' | System | 13 Aug 2020 20:36:23 |
| User entered '25'                                                                                                                                                                                                                          | System | 13 Aug 2020 20:36:23 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-13T16:36:17', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e83b742f-6575-4958-93bf-584276e120c6' | System | 13 Aug 2020 20:36:23 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 13 Aug 2020 20:36:23 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e83b742f-6575-4958-93bf-584276e120c6' | System | 13 Aug 2020 20:36:23 |
| User entered '13 Aug 2020 16:36'                                                                                                                                                                                                           | System | 13 Aug 2020 20:36:23 |



US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 4' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-14T18:21:36', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '76056529-4d46-48dd-8e90-71f5a300263b' | System | 14 Aug 2020 22:22:03 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 14 Aug 2020 22:22:03 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:34:14

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:21:40', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '76056529-4d46-48dd-8e90-71f5a300263b' | System | 14 Aug 2020 22:22:03 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 14 Aug 2020 22:22:03 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:21:43', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '76056529-4d46-48dd-8e90-71f5a300263b' | System | 14 Aug 2020 22:22:03 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 14 Aug 2020 22:22:03 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-14T18:21:55', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '76056529-4d46-48dd-8e90-71f5a300263b' | System | 14 Aug 2020 22:22:03 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 14 Aug 2020 22:22:03 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:22:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '76056529-4d46-48dd-8e90-71f5a300263b' | System | 14 Aug 2020 22:22:03 |
| User entered '14 Aug 2020 18:22'                                                                                                                                                                                                           | System | 14 Aug 2020 22:22:03 |



US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '15 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 5' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[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 (5546d99a3480aa1e)', Time: '2020-08-15T18:11:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '21b37c0d-85dd-4beb-9654-3fc6270db9ca' | System | 15 Aug 2020 22:11:59 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 15 Aug 2020 22:11:59 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:34:14

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:11:41', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '21b37c0d-85dd-4beb-9654-3fc6270db9ca' | System | 15 Aug 2020 22:11:59 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 15 Aug 2020 22:11:59 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:11:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '21b37c0d-85dd-4beb-9654-3fc6270db9ca' | System | 15 Aug 2020 22:11:59 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 15 Aug 2020 22:11:59 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-15T18:11:51', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '21b37c0d-85dd-4beb-9654-3fc6270db9ca' | System | 15 Aug 2020 22:11:59 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 15 Aug 2020 22:11:59 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:11:57', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '21b37c0d-85dd-4beb-9654-3fc6270db9ca' | System | 15 Aug 2020 22:11:59 |
| User entered '15 Aug 2020 18:11'                                                                                                                                                                                                           | System | 15 Aug 2020 22:11:59 |



US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '15 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 6' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-16T19:41:26', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6c146430-45d5-41da-806b-f1f9714eca28' | System | 16 Aug 2020 23:42:10 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 16 Aug 2020 23:42:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:34:14

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:41:30', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6c146430-45d5-41da-806b-f1f9714eca28' | System | 16 Aug 2020 23:42:10 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 16 Aug 2020 23:42:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:41:41', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6c146430-45d5-41da-806b-f1f9714eca28' | System | 16 Aug 2020 23:42:10 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 16 Aug 2020 23:42:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-16T19:42:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6c146430-45d5-41da-806b-f1f9714eca28' | System | 16 Aug 2020 23:42:10 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 16 Aug 2020 23:42:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6c146430-45d5-41da-806b-f1f9714eca28' | System | 16 Aug 2020 23:42:10 |
| User entered '16 Aug 2020 19:42'                                                                                                                                                                                                           | System | 16 Aug 2020 23:42:10 |



US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 7' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-17T17:32:27', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '4ab55426-bab1-4807-98d1-d44ad214e655' | System | 17 Aug 2020 21:33:10 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 17 Aug 2020 21:33:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:34:14

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:32:31', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '4ab55426-bab1-4807-98d1-d44ad214e655' | System | 17 Aug 2020 21:33:10 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 17 Aug 2020 21:33:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:32:33', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '4ab55426-bab1-4807-98d1-d44ad214e655' | System | 17 Aug 2020 21:33:10 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 17 Aug 2020 21:33:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-17T17:33:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '4ab55426-bab1-4807-98d1-d44ad214e655' | System | 17 Aug 2020 21:33:10 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 17 Aug 2020 21:33:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:07', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '4ab55426-bab1-4807-98d1-d44ad214e655' | System | 17 Aug 2020 21:33:10 |
| User entered '17 Aug 2020 17:33'                                                                                                                                                                                                           | System | 17 Aug 2020 21:33:10 |



US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:18:34', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a594cd0c-fc67-4456-8042-aea8f7565dbc' | System | 11 Aug 2020 22:20:02 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 11 Aug 2020 22:20:02 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:19:13', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a594cd0c-fc67-4456-8042-aea8f7565dbc' | System | 11 Aug 2020 22:20:02 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 11 Aug 2020 22:20:02 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:19:21', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a594cd0c-fc67-4456-8042-aea8f7565dbc' | System | 11 Aug 2020 22:20:02 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 11 Aug 2020 22:20:02 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:19:25', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a594cd0c-fc67-4456-8042-aea8f7565dbc' | System | 11 Aug 2020 22:20:02 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 11 Aug 2020 22:20:02 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:19:36', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a594cd0c-fc67-4456-8042-aea8f7565dbc' | System | 11 Aug 2020 22:20:02 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 11 Aug 2020 22:20:02 |



US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:19:39', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a594cd0c-fc67-4456-8042-aea8f7565dbc' | System | 11 Aug 2020 22:20:02 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 11 Aug 2020 22:20:02 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-11T18:19:48', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a594cd0c-fc67-4456-8042-aea8f7565dbc' | System | 11 Aug 2020 22:20:02 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 11 Aug 2020 22:20:02 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:19:57', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a594cd0c-fc67-4456-8042-aea8f7565dbc' | System | 11 Aug 2020 22:20:02 |
| User entered '11 Aug 2020 18:19'                                                                                                                                                                                                           | System | 11 Aug 2020 22:20:02 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 17:41' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 20:11' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

[TIMEPOINT](#)

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 1, after vaccination (at home)' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:32:47', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ed7deb85-9fe8-4ff4-b513-c6532d06ec65' | System | 12 Aug 2020 01:33:36 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 12 Aug 2020 01:33:36 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:32:59', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ed7deb85-9fe8-4ff4-b513-c6532d06ec65' | System | 12 Aug 2020 01:33:36 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Aug 2020 01:33:36 |



US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:33:06', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ed7deb85-9fe8-4ff4-b513-c6532d06ec65' | System | 12 Aug 2020 01:33:36 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Aug 2020 01:33:36 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:33:11', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ed7deb85-9fe8-4ff4-b513-c6532d06ec65' | System | 12 Aug 2020 01:33:36 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Aug 2020 01:33:36 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:33:14', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ed7deb85-9fe8-4ff4-b513-c6532d06ec65' | System | 12 Aug 2020 01:33:36 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Aug 2020 01:33:36 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:33:18', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ed7deb85-9fe8-4ff4-b513-c6532d06ec65' | System | 12 Aug 2020 01:33:36 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Aug 2020 01:33:36 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-11T21:33:28', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ed7deb85-9fe8-4ff4-b513-c6532d06ec65' | System | 12 Aug 2020 01:33:36 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 12 Aug 2020 01:33:36 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:33:34', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ed7deb85-9fe8-4ff4-b513-c6532d06ec65' | System | 12 Aug 2020 01:33:36 |
| User entered '11 Aug 2020 21:33'                                                                                                                                                                                                           | System | 12 Aug 2020 01:33:36 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Aug 2020 21:06' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |



US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 2' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:21:09', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a97626d3-add4-4915-9a2e-5b685a4472bd' | System | 12 Aug 2020 16:22:14 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 12 Aug 2020 16:22:14 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:21:33', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a97626d3-add4-4915-9a2e-5b685a4472bd' | System | 12 Aug 2020 16:22:14 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 12 Aug 2020 16:22:14 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:21:40', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a97626d3-add4-4915-9a2e-5b685a4472bd' | System | 12 Aug 2020 16:22:14 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Aug 2020 16:22:14 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:21:48', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a97626d3-add4-4915-9a2e-5b685a4472bd' | System | 12 Aug 2020 16:22:14 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Aug 2020 16:22:14 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:21:51', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a97626d3-add4-4915-9a2e-5b685a4472bd' | System | 12 Aug 2020 16:22:14 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Aug 2020 16:22:14 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

CHILLS

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:21:53', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a97626d3-add4-4915-9a2e-5b685a4472bd' | System | 12 Aug 2020 16:22:14 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Aug 2020 16:22:14 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-12T12:22:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a97626d3-add4-4915-9a2e-5b685a4472bd' | System | 12 Aug 2020 16:22:14 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 12 Aug 2020 16:22:14 |



US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:22:12', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a97626d3-add4-4915-9a2e-5b685a4472bd' | System | 12 Aug 2020 16:22:14 |
| User entered '12 Aug 2020 12:22'                                                                                                                                                                                                           | System | 12 Aug 2020 16:22:14 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 3' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:29', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '422e4635-fd9f-4de5-9e75-3bce4bee6876' | System | 13 Aug 2020 20:37:05 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 13 Aug 2020 20:37:05 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:32', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '422e4635-fd9f-4de5-9e75-3bce4bee6876' | System | 13 Aug 2020 20:37:05 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 13 Aug 2020 20:37:05 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:35', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '422e4635-fd9f-4de5-9e75-3bce4bee6876' | System | 13 Aug 2020 20:37:05 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 13 Aug 2020 20:37:05 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:40', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '422e4635-fd9f-4de5-9e75-3bce4bee6876' | System | 13 Aug 2020 20:37:05 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 13 Aug 2020 20:37:05 |



US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:42', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '422e4635-fd9f-4de5-9e75-3bce4bee6876' | System | 13 Aug 2020 20:37:05 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 13 Aug 2020 20:37:05 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:45', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '422e4635-fd9f-4de5-9e75-3bce4bee6876' | System | 13 Aug 2020 20:37:05 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 13 Aug 2020 20:37:05 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-13T16:36:55', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '422e4635-fd9f-4de5-9e75-3bce4bee6876' | System | 13 Aug 2020 20:37:05 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 13 Aug 2020 20:37:05 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:37:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '422e4635-fd9f-4de5-9e75-3bce4bee6876' | System | 13 Aug 2020 20:37:05 |
| User entered '13 Aug 2020 16:37'                                                                                                                                                                                                           | System | 13 Aug 2020 20:37:05 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 4' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:22:07', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '9bd44d2b-da85-4d90-a8af-91129639ab11' | System | 14 Aug 2020 22:23:02 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 14 Aug 2020 22:23:02 |



US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:22:11', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '9bd44d2b-da85-4d90-a8af-91129639ab11' | System | 14 Aug 2020 22:23:02 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 14 Aug 2020 22:23:02 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:22:14', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '9bd44d2b-da85-4d90-a8af-91129639ab11' | System | 14 Aug 2020 22:23:02 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 14 Aug 2020 22:23:02 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:22:43', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '9bd44d2b-da85-4d90-a8af-91129639ab11' | System | 14 Aug 2020 22:23:02 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 14 Aug 2020 22:23:02 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:22:45', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '9bd44d2b-da85-4d90-a8af-91129639ab11' | System | 14 Aug 2020 22:23:02 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 14 Aug 2020 22:23:02 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:22:49', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '9bd44d2b-da85-4d90-a8af-91129639ab11' | System | 14 Aug 2020 22:23:02 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 14 Aug 2020 22:23:02 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-14T18:22:54', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '9bd44d2b-da85-4d90-a8af-91129639ab11' | System | 14 Aug 2020 22:23:02 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 14 Aug 2020 22:23:02 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:23:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '9bd44d2b-da85-4d90-a8af-91129639ab11' | System | 14 Aug 2020 22:23:02 |
| User entered '14 Aug 2020 18:23'                                                                                                                                                                                                           | System | 14 Aug 2020 22:23:02 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |



US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '15 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 5' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:12:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a358e359-43d3-4280-bdd1-825442a0e058' | System | 15 Aug 2020 22:12:26 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 15 Aug 2020 22:12:26 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:12:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a358e359-43d3-4280-bdd1-825442a0e058' | System | 15 Aug 2020 22:12:26 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 15 Aug 2020 22:12:26 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:12:07', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a358e359-43d3-4280-bdd1-825442a0e058' | System | 15 Aug 2020 22:12:26 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 15 Aug 2020 22:12:26 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:12:09', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a358e359-43d3-4280-bdd1-825442a0e058' | System | 15 Aug 2020 22:12:26 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 15 Aug 2020 22:12:26 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:12:11', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a358e359-43d3-4280-bdd1-825442a0e058' | System | 15 Aug 2020 22:12:26 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 15 Aug 2020 22:12:26 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

CHILLS

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:12:13', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a358e359-43d3-4280-bdd1-825442a0e058' | System | 15 Aug 2020 22:12:26 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 15 Aug 2020 22:12:26 |



US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-15T18:12:19', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a358e359-43d3-4280-bdd1-825442a0e058' | System | 15 Aug 2020 22:12:26 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 15 Aug 2020 22:12:26 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:12:24', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a358e359-43d3-4280-bdd1-825442a0e058' | System | 15 Aug 2020 22:12:26 |
| User entered '15 Aug 2020 18:12'                                                                                                                                                                                                           | System | 15 Aug 2020 22:12:26 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '15 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 6' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:10', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c0dc92c-ba29-4828-b752-99225f4735ae' | System | 16 Aug 2020 23:43:01 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 16 Aug 2020 23:43:01 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:15', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c0dc92c-ba29-4828-b752-99225f4735ae' | System | 16 Aug 2020 23:43:01 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 16 Aug 2020 23:43:01 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:19', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c0dc92c-ba29-4828-b752-99225f4735ae' | System | 16 Aug 2020 23:43:01 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 16 Aug 2020 23:43:01 |



US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c0dc92c-ba29-4828-b752-99225f4735ae' | System | 16 Aug 2020 23:43:01 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 16 Aug 2020 23:43:01 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:25', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c0dc92c-ba29-4828-b752-99225f4735ae' | System | 16 Aug 2020 23:43:01 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 16 Aug 2020 23:43:01 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

CHILLS

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:28', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c0dc92c-ba29-4828-b752-99225f4735ae' | System | 16 Aug 2020 23:43:01 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 16 Aug 2020 23:43:01 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-16T19:42:54', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c0dc92c-ba29-4828-b752-99225f4735ae' | System | 16 Aug 2020 23:43:01 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 16 Aug 2020 23:43:01 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:58', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c0dc92c-ba29-4828-b752-99225f4735ae' | System | 16 Aug 2020 23:43:01 |
| User entered '16 Aug 2020 19:42'                                                                                                                                                                                                           | System | 16 Aug 2020 23:43:01 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 7' | System | 11 Aug 2020 22:10:10 |



US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:12', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a05cc05b-8b2a-4380-beab-7743edbfd1b3' | System | 17 Aug 2020 21:33:48 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 21:33:48 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:16', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a05cc05b-8b2a-4380-beab-7743edbfd1b3' | System | 17 Aug 2020 21:33:48 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 21:33:48 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:19', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a05cc05b-8b2a-4380-beab-7743edbfd1b3' | System | 17 Aug 2020 21:33:48 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 21:33:48 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:23', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a05cc05b-8b2a-4380-beab-7743edbfd1b3' | System | 17 Aug 2020 21:33:48 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 21:33:48 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:29', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a05cc05b-8b2a-4380-beab-7743edbfd1b3' | System | 17 Aug 2020 21:33:48 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 21:33:48 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

CHILLS

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:31', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a05cc05b-8b2a-4380-beab-7743edbfd1b3' | System | 17 Aug 2020 21:33:48 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 21:33:48 |

US3532002

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-08-17T17:33:40', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a05cc05b-8b2a-4380-beab-7743edbfd1b3' | System | 17 Aug 2020 21:33:48 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 17 Aug 2020 21:33:48 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a05cc05b-8b2a-4380-beab-7743edbfd1b3' | System | 17 Aug 2020 21:33:48 |
| User entered '17 Aug 2020 17:33'                                                                                                                                                                                                           | System | 17 Aug 2020 21:33:48 |



US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 12:00' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 11:59' | System | 11 Aug 2020 22:10:10 |

US3532002

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Was Contact Attempted?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4)<br>(b) (4) | 17 Aug 2020 22:39:45 |

US3532002

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:14

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                | User                  | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).               | (b) (4), (b) (6)      | 19 Aug 2020 01:54:21 |
| Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'In window' (Site from System). | Cindy Lubbers (b) (4) | 17 Aug 2020 22:40:44 |
| User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).               | System                | 17 Aug 2020 22:39:45 |
| User entered '17 Aug 2020'                                                                                                                                                                                                                           | Cindy Lubbers (b) (4) | 17 Aug 2020 22:39:45 |

US3532002

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--------------------------------------------|----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Cindy Lubbers (b) (4)<br>(b) (4) | 17 Aug 2020 22:39:45 |

US3532002

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Cindy Lubbers (b) (4)<br>(b) (4) | 17 Aug 2020 22:39:45 |

US3532002

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Cindy Lubbers (b) (4)<br>(b) (4) | 17 Aug 2020 22:40:55 |

US3532002

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Aug 2020 22:40:55 |



US3532002

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Was Contact Attempted?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 25 Aug 2020 23:05:56 |

US3532002

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '25 Aug 2020' | Etza Peters (b) (4)<br>(b) (4) | 25 Aug 2020 23:05:56 |

US3532002

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                           | Time (GMT)           |
|--------------------------------------------|--------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Etza Peters (b) (4)<br>(b) (4) | 25 Aug 2020 23:05:56 |

US3532002

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 25 Aug 2020 23:05:56 |

US3532002

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 25 Aug 2020 23:10:58 |

US3532002

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Aug 2020 23:10:58 |

US3532002

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Was Contact Attempted?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:58:06 |

US3532002

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| User entered '01 Sep 2020' reason for change: Data Entry Error | Kathy Stephens (b) (4) | 10 Nov 2020 23:40:55 |
| User entered '1 Sep 2020'                                      | Etza Peters (b) (4)    | 01 Sep 2020 18:58:06 |



US3532002

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                           | Time (GMT)           |
|--------------------------------------------|--------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:58:06 |

US3532002

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:58:06 |

US3532002

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:00:44 |

US3532002

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 01 Sep 2020 19:00:44 |

US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:34:14**

[Was this visit performed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:21:11 |

US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| User entered '8 Sep 2020' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:21:11 |

US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:21:11 |

US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:34:14**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 08 Sep 2020 12:21:11 |



US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[Timepoint](#)

| Audit                                            | User                           | Time (GMT)           |
|--------------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[Were vital signs assessed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| User entered '8 Sep 2020' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| User entered '07:40' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '8 Sep 2020 07:40' | System | 08 Sep 2020 12:24:03 |

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:14

Temperature (xxx.x)

| Audit                                                                                   | User                | Time (GMT)           |
|-----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System              | 08 Sep 2020 22:45:55 |
| User entered '98.5' F reason for change: Data Entry Error                               | Etza Peters (b) (4) | 08 Sep 2020 22:45:55 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System              | 08 Sep 2020 12:24:03 |
| User entered '98.5' (non-conformant).                                                   | Etza Peters (b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[Route of measurement](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (Oral)' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[If Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:24:03 |



US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[Pulse \(xxx\)](#)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '64' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '16' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit              | User                           | Time (GMT)           |
|--------------------|--------------------------------|----------------------|
| User entered '114' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '75' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 08 Sep 2020 12:24:03 |



US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[Timepoint](#)

| Audit                                              | User                           | Time (GMT)           |
|----------------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:24:03 |

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

[Were vital signs assessed?](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 08 Sep 2020 13:29:25 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 08 Sep 2020 13:29:25 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | Etza Peters (b) (4) | 08 Sep 2020 13:29:25 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 08 Sep 2020 12:24:03 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 08 Sep 2020 12:24:03 |

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

Date of assessment (*dd MMM yyyy*)

| Audit                                                                        | User                           | Time (GMT)           |
|------------------------------------------------------------------------------|--------------------------------|----------------------|
| User closed query 'Data is required. Please provide.'<br>(Site from System). | System                         | 08 Sep 2020 13:29:37 |
| User entered '8 Sep 2020' reason for change: Data<br>Entry Error             | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 13:29:37 |
| User opened query 'Data is required. Please provide.'<br>(Site from System). | System                         | 08 Sep 2020 13:29:25 |
| User entered empty.                                                          | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[Time of assessment \(00:00-23:59\)](#)

| Audit                                                    | User                | Time (GMT)           |
|----------------------------------------------------------|---------------------|----------------------|
| User entered '09:12' reason for change: Data Entry Error | Etza Peters (b) (4) | 08 Sep 2020 13:29:25 |
| User entered empty.                                      | Etza Peters (b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '8 Sep 2020 09:12' | System | 08 Sep 2020 13:29:37 |
| User entered empty.             | System | 08 Sep 2020 12:24:03 |

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

Temperature (xxx.x)

| Audit                                                                                   | User                | Time (GMT)           |
|-----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System              | 08 Sep 2020 13:29:37 |
| User entered '97.2' F reason for change: Data Entry Error                               | Etza Peters (b) (4) | 08 Sep 2020 13:29:37 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System              | 08 Sep 2020 13:29:25 |
| User entered '97.2' (non-conformant).                                                   | Etza Peters (b) (4) | 08 Sep 2020 13:29:25 |
| User entered empty.                                                                     | Etza Peters (b) (4) | 08 Sep 2020 12:24:03 |

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

[Route of measurement](#)

| Audit                                                                                        | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System              | 08 Sep 2020 13:29:43 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                     | 08 Sep 2020 13:29:43 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error                               | Etza Peters (b) (4) | 08 Sep 2020 13:29:43 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System              | 08 Sep 2020 13:29:37 |
| User entered empty.                                                                          | Etza Peters (b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[If Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:24:03 |



US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

[Pulse \(xxx\)](#)

| Audit                                                 | User                | Time (GMT)           |
|-------------------------------------------------------|---------------------|----------------------|
| User entered '61' reason for change: Data Entry Error | Etza Peters (b) (4) | 08 Sep 2020 13:29:25 |
| User entered empty.                                   | Etza Peters (b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'bpm'  | System | 08 Sep 2020 13:29:25 |
| User entered empty. | System | 08 Sep 2020 12:24:03 |

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                 | User                | Time (GMT)           |
|-------------------------------------------------------|---------------------|----------------------|
| User entered '16' reason for change: Data Entry Error | Etza Peters (b) (4) | 08 Sep 2020 13:29:25 |
| User entered empty.                                   | Etza Peters (b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 08 Sep 2020 13:29:25 |
| User entered empty.        | System | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                                                  | User                | Time (GMT)           |
|--------------------------------------------------------|---------------------|----------------------|
| User entered '111' reason for change: Data Entry Error | Etza Peters (b) (4) | 08 Sep 2020 13:29:25 |
| User entered empty.                                    | Etza Peters (b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 08 Sep 2020 13:29:25 |
| User entered empty. | System | 08 Sep 2020 12:24:03 |

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                 | User                | Time (GMT)           |
|-------------------------------------------------------|---------------------|----------------------|
| User entered '73' reason for change: Data Entry Error | Etza Peters (b) (4) | 08 Sep 2020 13:29:25 |
| User entered empty.                                   | Etza Peters (b) (4) | 08 Sep 2020 12:24:03 |

US3532002

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:34:14**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 08 Sep 2020 13:29:25 |
| User entered empty. | System | 08 Sep 2020 12:24:03 |



US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:34:14**

[Was the physical examination performed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:21:20 |

US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:34:14**

[Date of examination \(dd MMM yyyy\)](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| User entered '8 Sep 2020' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:21:20 |

US3532002

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:14

[Was study treatment given?](#)

| Audit                                                                                                                                                                                             | User                | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).             | System              | 08 Sep 2020 12:52:12 |
| Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System). | System              | 08 Sep 2020 12:52:12 |
| User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).             | System              | 08 Sep 2020 12:49:08 |
| User entered 'Yes (Y)'                                                                                                                                                                            | Etza Peters (b) (4) | 08 Sep 2020 12:49:08 |

US3532002

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:34:14

[If No, reason not given](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:49:08 |

US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:49:08 |

US3532002

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:34:14

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 08 Sep 2020 12:49:08 |

US3532002

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:14

What was the treatment date? (dd MMM yyyy)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| User entered '8 Sep 2020' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:49:08 |

US3532002

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:34:14

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                                                    | User                | Time (GMT)           |
|----------------------------------------------------------|---------------------|----------------------|
| User entered '08:40' reason for change: Data Entry Error | Etza Peters (b) (4) | 08 Sep 2020 12:52:12 |
| User entered empty.                                      | Etza Peters (b) (4) | 08 Sep 2020 12:49:08 |



US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:34:14**

[Treatment Date and Time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '8 Sep 2020 08:40' | System | 08 Sep 2020 12:52:12 |
| User entered empty.             | System | 08 Sep 2020 12:49:08 |

US3532002

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:14

[Which arm was used to give treatment?](#)

| Audit                              | User                           | Time (GMT)           |
|------------------------------------|--------------------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:49:08 |

US3532002

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:34:14

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 08 Sep 2020 12:49:08 |

US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:34:14**

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 08 Sep 2020 12:49:08 |

US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:34:14**

[Was the sample collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:24:22 |

US3532002

**Folder:** Visit 2 Day 29 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 09:34:14

**Collection date** (*dd MMM yyyy*)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| User entered '8 Sep 2020' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:24:22 |

US3532002

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:14

Collection time (00:00-23:59)

| Audit                                                    | User                | Time (GMT)           |
|----------------------------------------------------------|---------------------|----------------------|
| User entered '08:07' reason for change: Data Entry Error | Etza Peters (b) (4) | 08 Sep 2020 12:25:41 |
| User entered '07:51'                                     | Etza Peters (b) (4) | 08 Sep 2020 12:24:22 |

US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '8 Sep 2020 08:07' | System | 08 Sep 2020 12:25:41 |
| User entered '8 Sep 2020 07:51' | System | 08 Sep 2020 12:24:22 |



US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                     | User                | Time (GMT)           |
|---------------------------|---------------------|----------------------|
| User entered '8 Sep 2020' | Etza Peters (b) (4) | 08 Sep 2020 12:25:22 |
|                           | (b) (4)             |                      |

US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Lab Test](#)

| Audit                                                        | User                | Time (GMT)           |
|--------------------------------------------------------------|---------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Etza Peters (b) (4) | 08 Sep 2020 12:25:22 |

US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Was the sample collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:25:22 |

US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Collection time \(00:00 - 23:59\)](#)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| User entered '07:51' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:25:22 |

US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '8 Sep 2020 07:51' | System | 08 Sep 2020 12:25:22 |

US3532002

**Folder:** Visit 2 Day 29 (1)

**Form:** Central Laboratory - Nasopharyngeal Swab (2)

**Generated On:** 26 Nov 2020 09:34:14

[Lab Test](#)

| Audit                                                        | User                | Time (GMT)           |
|--------------------------------------------------------------|---------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Etza Peters (b) (4) | 08 Sep 2020 12:25:22 |

US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Was the sample collected?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:25:22 |

US3532002

**Folder:** Visit 2 Day 29 (1)

**Form:** Central Laboratory - Nasopharyngeal Swab (2)

**Generated On:** 26 Nov 2020 09:34:14

[Collection time \(00:00 - 23:59\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 12:25:22 |



US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Sep 2020 12:25:22 |

US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 08 Sep 2020 13:29:49 |

US3532002

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Sep 2020 13:29:49 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:15:52', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f942c075-8fcb-4e44-9f2f-b96fafd0b1d8' | System | 08 Sep 2020 13:16:15 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 08 Sep 2020 13:16:15 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:16:01', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f942c075-8fcb-4e44-9f2f-b96fafd0b1d8' | System | 08 Sep 2020 13:16:15 |
| User entered '97.2'                                                                                                                                                                                                                        | System | 08 Sep 2020 13:16:15 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:16:06', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f942c075-8fcb-4e44-9f2f-b96fafd0b1d8' | System | 08 Sep 2020 13:16:15 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 08 Sep 2020 13:16:15 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:16:12', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f942c075-8fcb-4e44-9f2f-b96fafd0b1d8' | System | 08 Sep 2020 13:16:15 |
| User entered '08 Sep 2020 09:16'                                                                                                                                                                                                           | System | 08 Sep 2020 13:16:15 |



US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 09:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:30' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 1, after vaccination (at home)' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:06:14', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b6c85710-c427-42a1-9d96-32c2e294f86d' | System | 08 Sep 2020 23:06:33 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 08 Sep 2020 23:06:33 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:06:21', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b6c85710-c427-42a1-9d96-32c2e294f86d' User entered '97.6' | System | 08 Sep 2020 23:06:33 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:06:25', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b6c85710-c427-42a1-9d96-32c2e294f86d' | System | 08 Sep 2020 23:06:33 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 08 Sep 2020 23:06:33 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:06:30', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b6c85710-c427-42a1-9d96-32c2e294f86d' | System | 08 Sep 2020 23:06:33 |
| User entered '08 Sep 2020 19:06'                                                                                                                                                                                                           | System | 08 Sep 2020 23:06:33 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:25' | System | 08 Sep 2020 12:52:12 |



US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 2' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:34:14

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:52:46', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8fb43577-23be-40d6-b7e5-1304d58c76f3' | System | 09 Sep 2020 20:53:10 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 09 Sep 2020 20:53:10 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:34:14

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:52:57', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8fb43577-23be-40d6-b7e5-1304d58c76f3' | System | 09 Sep 2020 20:53:10 |
| User entered '98.8'                                                                                                                                                                                                                        | System | 09 Sep 2020 20:53:10 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:53:03', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8fb43577-23be-40d6-b7e5-1304d58c76f3' | System | 09 Sep 2020 20:53:10 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 09 Sep 2020 20:53:10 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:53:09', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8fb43577-23be-40d6-b7e5-1304d58c76f3' | System | 09 Sep 2020 20:53:10 |
| User entered '09 Sep 2020 16:53'                                                                                                                                                                                                           | System | 09 Sep 2020 20:53:10 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |



US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 3' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:34:14

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:12:11', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a4e29251-e465-4978-8f78-11bbfe341f0b' | System | 10 Sep 2020 20:12:28 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 10 Sep 2020 20:12:28 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:34:14

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:12:16', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a4e29251-e465-4978-8f78-11bbfe341f0b' | System | 10 Sep 2020 20:12:28 |
| User entered '97.4'                                                                                                                                                                                                                        | System | 10 Sep 2020 20:12:28 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:12:20', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a4e29251-e465-4978-8f78-11bbfe341f0b' | System | 10 Sep 2020 20:12:28 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 10 Sep 2020 20:12:28 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:12:25', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a4e29251-e465-4978-8f78-11bbfe341f0b' | System | 10 Sep 2020 20:12:28 |
| User entered '10 Sep 2020 16:12'                                                                                                                                                                                                           | System | 10 Sep 2020 20:12:28 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 4' | System | 08 Sep 2020 12:52:12 |



US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:34:14

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:32:34', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '70cf157e-d11f-4c66-8b27-5a0818041f31' | System | 12 Sep 2020 01:34:58 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 12 Sep 2020 01:34:58 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:34:47', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '70cf157e-d11f-4c66-8b27-5a0818041f31' | System | 12 Sep 2020 01:34:58 |
| User entered '97.2'                                                                                                                                                                                                                        | System | 12 Sep 2020 01:34:58 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:34:51', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '70cf157e-d11f-4c66-8b27-5a0818041f31' | System | 12 Sep 2020 01:34:58 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 12 Sep 2020 01:34:58 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:34:56', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '70cf157e-d11f-4c66-8b27-5a0818041f31' | System | 12 Sep 2020 01:34:58 |
| User entered '11 Sep 2020 21:34'                                                                                                                                                                                                           | System | 12 Sep 2020 01:34:58 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 5' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:34:14

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:05', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '10ed855d-3aad-49ec-9fcb-b332b7999dce' | System | 12 Sep 2020 20:56:23 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 12 Sep 2020 20:56:23 |



US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:34:14

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:12', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '10ed855d-3aad-49ec-9fcb-b332b7999dce' | System | 12 Sep 2020 20:56:23 |
| User entered '97.9'                                                                                                                                                                                                                        | System | 12 Sep 2020 20:56:23 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:16', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '10ed855d-3aad-49ec-9fcb-b332b7999dce' | System | 12 Sep 2020 20:56:23 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 12 Sep 2020 20:56:23 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:21', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '10ed855d-3aad-49ec-9fcb-b332b7999dce' | System | 12 Sep 2020 20:56:23 |
| User entered '12 Sep 2020 16:56'                                                                                                                                                                                                           | System | 12 Sep 2020 20:56:23 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 6' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:34:14

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:55:56', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'da791032-a389-499e-a200-9bc8644c7a08' | System | 13 Sep 2020 22:56:29 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 13 Sep 2020 22:56:29 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:34:14

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:19', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'da791032-a389-499e-a200-9bc8644c7a08' | System | 13 Sep 2020 22:56:29 |
| User entered '97.9'                                                                                                                                                                                                                        | System | 13 Sep 2020 22:56:29 |



US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'da791032-a389-499e-a200-9bc8644c7a08' | System | 13 Sep 2020 22:56:29 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 13 Sep 2020 22:56:29 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:26', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'da791032-a389-499e-a200-9bc8644c7a08' | System | 13 Sep 2020 22:56:29 |
| User entered '13 Sep 2020 18:56'                                                                                                                                                                                                           | System | 13 Sep 2020 22:56:29 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 7' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:34:14

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:06:08', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de2eabb9-2119-408f-b7e9-e363d3878fb7' | System | 14 Sep 2020 22:07:15 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 14 Sep 2020 22:07:15 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:34:14

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:05', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de2eabb9-2119-408f-b7e9-e363d3878fb7' | System | 14 Sep 2020 22:07:15 |
| User entered '98.0'                                                                                                                                                                                                                        | System | 14 Sep 2020 22:07:15 |

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:09', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de2eabb9-2119-408f-b7e9-e363d3878fb7' | System | 14 Sep 2020 22:07:15 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 14 Sep 2020 22:07:15 |



US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:14', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de2eabb9-2119-408f-b7e9-e363d3878fb7' | System | 14 Sep 2020 22:07:15 |
| User entered '14 Sep 2020 18:07'                                                                                                                                                                                                           | System | 14 Sep 2020 22:07:15 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '15 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-08T09:16:24', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1ef32bf-1857-4ad8-a477-438a21b66572' | System | 08 Sep 2020 13:16:51 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 08 Sep 2020 13:16:51 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:16:27', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1ef32bf-1857-4ad8-a477-438a21b66572' | System | 08 Sep 2020 13:16:51 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 08 Sep 2020 13:16:51 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:16:31', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1ef32bf-1857-4ad8-a477-438a21b66572' | System | 08 Sep 2020 13:16:51 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 08 Sep 2020 13:16:51 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-08T09:16:42', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1ef32bf-1857-4ad8-a477-438a21b66572' | System | 08 Sep 2020 13:16:51 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 08 Sep 2020 13:16:51 |



US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:16:47', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1ef32bf-1857-4ad8-a477-438a21b66572' | System | 08 Sep 2020 13:16:51 |
| User entered '08 Sep 2020 09:16'                                                                                                                                                                                                           | System | 08 Sep 2020 13:16:51 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 09:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:30' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 1, after vaccination (at home)' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-08T19:11:18', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e4bde11-3a1a-4e36-9d77-8c30476c2195' | System | 08 Sep 2020 23:12:48 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 08 Sep 2020 23:12:48 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:11:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e4bde11-3a1a-4e36-9d77-8c30476c2195' | System | 08 Sep 2020 23:12:48 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 08 Sep 2020 23:12:48 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:11:26', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e4bde11-3a1a-4e36-9d77-8c30476c2195' | System | 08 Sep 2020 23:12:48 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 08 Sep 2020 23:12:48 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

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

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:11:42', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e4bde11-3a1a-4e36-9d77-8c30476c2195' | System | 08 Sep 2020 23:12:48 |
| User entered '4'                                                                                                                                                                                                                           | System | 08 Sep 2020 23:12:48 |



US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-08T19:12:39', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e4bde11-3a1a-4e36-9d77-8c30476c2195' | System | 08 Sep 2020 23:12:48 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 08 Sep 2020 23:12:48 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:12:45', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e4bde11-3a1a-4e36-9d77-8c30476c2195' | System | 08 Sep 2020 23:12:48 |
| User entered '08 Sep 2020 19:12'                                                                                                                                                                                                           | System | 08 Sep 2020 23:12:48 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:25' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 2' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[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 (5546d99a3480aa1e)', Time: '2020-09-09T16:53:48', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '23f70677-7580-4c2d-a2ce-81d395a241d2' | System | 09 Sep 2020 20:56:07 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 09 Sep 2020 20:56:07 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:34:14

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:53:54', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '23f70677-7580-4c2d-a2ce-81d395a241d2' | System | 09 Sep 2020 20:56:07 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 09 Sep 2020 20:56:07 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:55:30', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '23f70677-7580-4c2d-a2ce-81d395a241d2' | System | 09 Sep 2020 20:56:07 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 09 Sep 2020 20:56:07 |



US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:34:14

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

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:55:49', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '23f70677-7580-4c2d-a2ce-81d395a241d2' | System | 09 Sep 2020 20:56:07 |
| User entered '5'                                                                                                                                                                                                                           | System | 09 Sep 2020 20:56:07 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-09T16:55:34', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '23f70677-7580-4c2d-a2ce-81d395a241d2' | System | 09 Sep 2020 20:56:07 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 09 Sep 2020 20:56:07 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:56:05', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '23f70677-7580-4c2d-a2ce-81d395a241d2' | System | 09 Sep 2020 20:56:07 |
| User entered '09 Sep 2020 16:56'                                                                                                                                                                                                           | System | 09 Sep 2020 20:56:07 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 3' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[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 (5546d99a3480aa1e)', Time: '2020-09-10T16:12:33', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6b65c745-24ac-4c89-b2d9-b6415d3eb1ec' | System | 10 Sep 2020 20:13:47 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 10 Sep 2020 20:13:47 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:34:14

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:12:38', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6b65c745-24ac-4c89-b2d9-b6415d3eb1ec' | System | 10 Sep 2020 20:13:47 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 10 Sep 2020 20:13:47 |



US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:12:42', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6b65c745-24ac-4c89-b2d9-b6415d3eb1ec' | System | 10 Sep 2020 20:13:47 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 10 Sep 2020 20:13:47 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:13:29', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6b65c745-24ac-4c89-b2d9-b6415d3eb1ec' | System | 10 Sep 2020 20:13:47 |
| User entered '5'                                                                                                                                                                                                                           | System | 10 Sep 2020 20:13:47 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-10T16:13:40', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6b65c745-24ac-4c89-b2d9-b6415d3eb1ec' | System | 10 Sep 2020 20:13:47 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 10 Sep 2020 20:13:47 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:13:45', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6b65c745-24ac-4c89-b2d9-b6415d3eb1ec' | System | 10 Sep 2020 20:13:47 |
| User entered '10 Sep 2020 16:13'                                                                                                                                                                                                           | System | 10 Sep 2020 20:13:47 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 4' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-11T21:35:13', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '61135e64-40e7-469b-afdf-0ff953ff5c3f' | System | 12 Sep 2020 01:36:05 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                        | System | 12 Sep 2020 01:36:05 |



US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:34:14

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:35:17', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '61135e64-40e7-469b-afdf-0ff953ff5c3f' | System | 12 Sep 2020 01:36:05 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 12 Sep 2020 01:36:05 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:35:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '61135e64-40e7-469b-afdf-0ff953ff5c3f' | System | 12 Sep 2020 01:36:05 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 12 Sep 2020 01:36:05 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:34:14

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

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

| Audit                                                                                                                                                                                                                                                        | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:35:46', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '61135e64-40e7-469b-afdf-0ff953ff5c3f' User entered '30' | System | 12 Sep 2020 01:36:05 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-11T21:35:55', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '61135e64-40e7-469b-afdf-0ff953ff5c3f' | System | 12 Sep 2020 01:36:05 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 12 Sep 2020 01:36:05 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '61135e64-40e7-469b-afdf-0ff953ff5c3f' | System | 12 Sep 2020 01:36:05 |
| User entered '11 Sep 2020 21:36'                                                                                                                                                                                                           | System | 12 Sep 2020 01:36:05 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 5' | System | 08 Sep 2020 12:52:12 |



US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-12T16:56:29', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1ae92e04-cb71-4c9a-963e-7a6a389cd715' | System | 12 Sep 2020 20:56:46 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 12 Sep 2020 20:56:46 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:34:14

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:33', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1ae92e04-cb71-4c9a-963e-7a6a389cd715' | System | 12 Sep 2020 20:56:46 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 12 Sep 2020 20:56:46 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:35', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1ae92e04-cb71-4c9a-963e-7a6a389cd715' | System | 12 Sep 2020 20:56:46 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 12 Sep 2020 20:56:46 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-12T16:56:39', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1ae92e04-cb71-4c9a-963e-7a6a389cd715' | System | 12 Sep 2020 20:56:46 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 12 Sep 2020 20:56:46 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1ae92e04-cb71-4c9a-963e-7a6a389cd715' | System | 12 Sep 2020 20:56:46 |
| User entered '12 Sep 2020 16:56'                                                                                                                                                                                                           | System | 12 Sep 2020 20:56:46 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 6' | System | 08 Sep 2020 12:52:12 |



US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-13T18:56:32', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'd8df50ed-a5f0-4ee8-9ef7-9265904b71a0' | System | 13 Sep 2020 22:56:50 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 13 Sep 2020 22:56:50 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:34:14

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:35', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'd8df50ed-a5f0-4ee8-9ef7-9265904b71a0' | System | 13 Sep 2020 22:56:50 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 13 Sep 2020 22:56:50 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:39', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'd8df50ed-a5f0-4ee8-9ef7-9265904b71a0' | System | 13 Sep 2020 22:56:50 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 13 Sep 2020 22:56:50 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-13T18:56:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'd8df50ed-a5f0-4ee8-9ef7-9265904b71a0' | System | 13 Sep 2020 22:56:50 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 13 Sep 2020 22:56:50 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:48', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'd8df50ed-a5f0-4ee8-9ef7-9265904b71a0' | System | 13 Sep 2020 22:56:50 |
| User entered '13 Sep 2020 18:56'                                                                                                                                                                                                           | System | 13 Sep 2020 22:56:50 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 7' | System | 08 Sep 2020 12:52:12 |



US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[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 (5546d99a3480aa1e)', Time: '2020-09-14T18:07:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5665902c-be2b-45c5-8591-ecf1b8a57b4e' | System | 14 Sep 2020 22:07:52 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 14 Sep 2020 22:07:52 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:34:14

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:26', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5665902c-be2b-45c5-8591-ecf1b8a57b4e' | System | 14 Sep 2020 22:07:52 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 14 Sep 2020 22:07:52 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:34:14

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:33', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5665902c-be2b-45c5-8591-ecf1b8a57b4e' | System | 14 Sep 2020 22:07:52 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 14 Sep 2020 22:07:52 |

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-14T18:07:42', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5665902c-be2b-45c5-8591-ecf1b8a57b4e' | System | 14 Sep 2020 22:07:52 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 14 Sep 2020 22:07:52 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:47', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5665902c-be2b-45c5-8591-ecf1b8a57b4e' | System | 14 Sep 2020 22:07:52 |
| User entered '14 Sep 2020 18:07'                                                                                                                                                                                                           | System | 14 Sep 2020 22:07:52 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '15 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 08 Sep 2020 12:52:12 |



US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:16:53', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '937ed021-75ec-4d98-8031-3b0ea56b8907' | System | 08 Sep 2020 13:17:57 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 08 Sep 2020 13:17:57 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:17:16', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '937ed021-75ec-4d98-8031-3b0ea56b8907' | System | 08 Sep 2020 13:17:57 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 08 Sep 2020 13:17:57 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:17:24', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '937ed021-75ec-4d98-8031-3b0ea56b8907' | System | 08 Sep 2020 13:17:57 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 08 Sep 2020 13:17:57 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:17:38', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '937ed021-75ec-4d98-8031-3b0ea56b8907' | System | 08 Sep 2020 13:17:57 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 08 Sep 2020 13:17:57 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:17:41', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '937ed021-75ec-4d98-8031-3b0ea56b8907' | System | 08 Sep 2020 13:17:57 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 08 Sep 2020 13:17:57 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:17:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '937ed021-75ec-4d98-8031-3b0ea56b8907' | System | 08 Sep 2020 13:17:57 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 08 Sep 2020 13:17:57 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-08T09:17:49', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '937ed021-75ec-4d98-8031-3b0ea56b8907' | System | 08 Sep 2020 13:17:57 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 08 Sep 2020 13:17:57 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:34:14

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:17:55', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '937ed021-75ec-4d98-8031-3b0ea56b8907' | System | 08 Sep 2020 13:17:57 |
| User entered '08 Sep 2020 09:17'                                                                                                                                                                                                           | System | 08 Sep 2020 13:17:57 |



US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 09:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:30' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 1, after vaccination (at home)' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:12:53', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'fe6677a9-2f5b-412b-be58-37872b19f289' | System | 08 Sep 2020 23:13:27 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 08 Sep 2020 23:13:27 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:12:59', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'fe6677a9-2f5b-412b-be58-37872b19f289' | System | 08 Sep 2020 23:13:27 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 08 Sep 2020 23:13:27 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:13:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'fe6677a9-2f5b-412b-be58-37872b19f289' | System | 08 Sep 2020 23:13:27 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 08 Sep 2020 23:13:27 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:13:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'fe6677a9-2f5b-412b-be58-37872b19f289' User entered 'None (0)' | System | 08 Sep 2020 23:13:27 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:13:06', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'fe6677a9-2f5b-412b-be58-37872b19f289' | System | 08 Sep 2020 23:13:27 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 08 Sep 2020 23:13:27 |



US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

CHILLS

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:13:09', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'fe6677a9-2f5b-412b-be58-37872b19f289' | System | 08 Sep 2020 23:13:27 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 08 Sep 2020 23:13:27 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-08T19:13:17', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'fe6677a9-2f5b-412b-be58-37872b19f289' | System | 08 Sep 2020 23:13:27 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 08 Sep 2020 23:13:27 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:13:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'fe6677a9-2f5b-412b-be58-37872b19f289' | System | 08 Sep 2020 23:13:27 |
| User entered '08 Sep 2020 19:13'                                                                                                                                                                                                           | System | 08 Sep 2020 23:13:27 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:25' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 2' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:56:12', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ce763bd8-fc7c-4f2c-9c20-742d68aac117' | System | 09 Sep 2020 20:57:05 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 09 Sep 2020 20:57:05 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:56:21', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ce763bd8-fc7c-4f2c-9c20-742d68aac117' | System | 09 Sep 2020 20:57:05 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                         | System | 09 Sep 2020 20:57:05 |



US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:56:30', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ce763bd8-fc7c-4f2c-9c20-742d68aac117' | System | 09 Sep 2020 20:57:05 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 09 Sep 2020 20:57:05 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:56:35', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ce763bd8-fc7c-4f2c-9c20-742d68aac117' | System | 09 Sep 2020 20:57:05 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 09 Sep 2020 20:57:05 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:56:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ce763bd8-fc7c-4f2c-9c20-742d68aac117' | System | 09 Sep 2020 20:57:05 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 09 Sep 2020 20:57:05 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:56:49', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ce763bd8-fc7c-4f2c-9c20-742d68aac117' | System | 09 Sep 2020 20:57:05 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 09 Sep 2020 20:57:05 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-09T16:56:57', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ce763bd8-fc7c-4f2c-9c20-742d68aac117' | System | 09 Sep 2020 20:57:05 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 09 Sep 2020 20:57:05 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:57:03', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ce763bd8-fc7c-4f2c-9c20-742d68aac117' | System | 09 Sep 2020 20:57:05 |
| User entered '09 Sep 2020 16:57'                                                                                                                                                                                                           | System | 09 Sep 2020 20:57:05 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |



US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 3' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:13:50', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '43bff529-0175-4872-9619-651e1f57be30' | System | 10 Sep 2020 20:14:38 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                           | System | 10 Sep 2020 20:14:38 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:14:08', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '43bff529-0175-4872-9619-651e1f57be30' | System | 10 Sep 2020 20:14:38 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 10 Sep 2020 20:14:38 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:14:13', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '43bff529-0175-4872-9619-651e1f57be30' | System | 10 Sep 2020 20:14:38 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 10 Sep 2020 20:14:38 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:14:16', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '43bff529-0175-4872-9619-651e1f57be30' | System | 10 Sep 2020 20:14:38 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 10 Sep 2020 20:14:38 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:14:19', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '43bff529-0175-4872-9619-651e1f57be30' | System | 10 Sep 2020 20:14:38 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 10 Sep 2020 20:14:38 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

CHILLS

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:14:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '43bff529-0175-4872-9619-651e1f57be30' | System | 10 Sep 2020 20:14:38 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 10 Sep 2020 20:14:38 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-10T16:14:29', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '43bff529-0175-4872-9619-651e1f57be30' | System | 10 Sep 2020 20:14:38 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 10 Sep 2020 20:14:38 |



US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:14:34', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '43bff529-0175-4872-9619-651e1f57be30' | System | 10 Sep 2020 20:14:38 |
| User entered '10 Sep 2020 16:14'                                                                                                                                                                                                           | System | 10 Sep 2020 20:14:38 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 4' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:15', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ff130702-1a72-4d00-b778-33e63631c058' | System | 12 Sep 2020 01:36:41 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Sep 2020 01:36:41 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:19', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ff130702-1a72-4d00-b778-33e63631c058' | System | 12 Sep 2020 01:36:41 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Sep 2020 01:36:41 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ff130702-1a72-4d00-b778-33e63631c058' | System | 12 Sep 2020 01:36:41 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Sep 2020 01:36:41 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:26', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ff130702-1a72-4d00-b778-33e63631c058' | System | 12 Sep 2020 01:36:41 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Sep 2020 01:36:41 |



US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:29', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ff130702-1a72-4d00-b778-33e63631c058' | System | 12 Sep 2020 01:36:41 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Sep 2020 01:36:41 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:31', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ff130702-1a72-4d00-b778-33e63631c058' | System | 12 Sep 2020 01:36:41 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Sep 2020 01:36:41 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-11T21:36:34', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ff130702-1a72-4d00-b778-33e63631c058' | System | 12 Sep 2020 01:36:41 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 12 Sep 2020 01:36:41 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:34:14

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:39', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ff130702-1a72-4d00-b778-33e63631c058' | System | 12 Sep 2020 01:36:41 |
| User entered '11 Sep 2020 21:36'                                                                                                                                                                                                           | System | 12 Sep 2020 01:36:41 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 5' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:49', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '90672760-5ddb-4e83-bf34-8f094af4d94d' | System | 12 Sep 2020 20:57:38 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Sep 2020 20:57:38 |



US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:51', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '90672760-5ddb-4e83-bf34-8f094af4d94d' | System | 12 Sep 2020 20:57:38 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Sep 2020 20:57:38 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:54', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '90672760-5ddb-4e83-bf34-8f094af4d94d' | System | 12 Sep 2020 20:57:38 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Sep 2020 20:57:38 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:57', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '90672760-5ddb-4e83-bf34-8f094af4d94d' | System | 12 Sep 2020 20:57:38 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Sep 2020 20:57:38 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:57:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '90672760-5ddb-4e83-bf34-8f094af4d94d' | System | 12 Sep 2020 20:57:38 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Sep 2020 20:57:38 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:57:03', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '90672760-5ddb-4e83-bf34-8f094af4d94d' | System | 12 Sep 2020 20:57:38 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 12 Sep 2020 20:57:38 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

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 (5546d99a3480aa1e)', Time: '2020-09-12T16:57:31', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '90672760-5ddb-4e83-bf34-8f094af4d94d' | System | 12 Sep 2020 20:57:38 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 12 Sep 2020 20:57:38 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:34:14

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:57:35', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '90672760-5ddb-4e83-bf34-8f094af4d94d' | System | 12 Sep 2020 20:57:38 |
| User entered '12 Sep 2020 16:57'                                                                                                                                                                                                           | System | 12 Sep 2020 20:57:38 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |



US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 6' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:52', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de39f6ee-6f44-42de-ba2e-c0c525fe4359' | System | 13 Sep 2020 22:57:19 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 13 Sep 2020 22:57:19 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:55', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de39f6ee-6f44-42de-ba2e-c0c525fe4359' | System | 13 Sep 2020 22:57:19 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 13 Sep 2020 22:57:19 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:59', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de39f6ee-6f44-42de-ba2e-c0c525fe4359' | System | 13 Sep 2020 22:57:19 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 13 Sep 2020 22:57:19 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:57:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de39f6ee-6f44-42de-ba2e-c0c525fe4359' | System | 13 Sep 2020 22:57:19 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 13 Sep 2020 22:57:19 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:57:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de39f6ee-6f44-42de-ba2e-c0c525fe4359' | System | 13 Sep 2020 22:57:19 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 13 Sep 2020 22:57:19 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

CHILLS

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:57:07', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de39f6ee-6f44-42de-ba2e-c0c525fe4359' | System | 13 Sep 2020 22:57:19 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 13 Sep 2020 22:57:19 |



US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-13T18:57:14', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de39f6ee-6f44-42de-ba2e-c0c525fe4359' | System | 13 Sep 2020 22:57:19 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 13 Sep 2020 22:57:19 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:34:14

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:57:17', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de39f6ee-6f44-42de-ba2e-c0c525fe4359' | System | 13 Sep 2020 22:57:19 |
| User entered '13 Sep 2020 18:57'                                                                                                                                                                                                           | System | 13 Sep 2020 22:57:19 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '13 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 08 Sep 2020 12:52:12 |
| User entered 'Day 7' | System | 08 Sep 2020 12:52:12 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:52', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1b22e2e2-9e12-41ee-b05e-6eb0f3344f26' | System | 14 Sep 2020 22:08:22 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 14 Sep 2020 22:08:22 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:54', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1b22e2e2-9e12-41ee-b05e-6eb0f3344f26' | System | 14 Sep 2020 22:08:22 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 14 Sep 2020 22:08:22 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:58', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1b22e2e2-9e12-41ee-b05e-6eb0f3344f26' | System | 14 Sep 2020 22:08:22 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 14 Sep 2020 22:08:22 |



US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:08:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1b22e2e2-9e12-41ee-b05e-6eb0f3344f26' | System | 14 Sep 2020 22:08:22 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 14 Sep 2020 22:08:22 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:08:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1b22e2e2-9e12-41ee-b05e-6eb0f3344f26' | System | 14 Sep 2020 22:08:22 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 14 Sep 2020 22:08:22 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:08:05', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1b22e2e2-9e12-41ee-b05e-6eb0f3344f26' | System | 14 Sep 2020 22:08:22 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 14 Sep 2020 22:08:22 |

US3532002

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:34:14

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 (5546d99a3480aa1e)', Time: '2020-09-14T18:08:15', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1b22e2e2-9e12-41ee-b05e-6eb0f3344f26' | System | 14 Sep 2020 22:08:22 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 14 Sep 2020 22:08:22 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:08:19', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1b22e2e2-9e12-41ee-b05e-6eb0f3344f26' | System | 14 Sep 2020 22:08:22 |
| User entered '14 Sep 2020 18:08'                                                                                                                                                                                                           | System | 14 Sep 2020 22:08:22 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '14 Sep 2020 12:00' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:34:14**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '15 Sep 2020 11:59' | System | 08 Sep 2020 12:52:12 |

US3532002

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Was Contact Attempted?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:40:31 |



US3532002

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '15 Sep 2020' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:40:31 |

US3532002

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                          | Time (GMT)           |
|--------------------------------------------|-------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:40:31 |

US3532002

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:40:31 |

US3532002

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:40:40 |

US3532002

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Oct 2020 17:40:40 |

US3532002

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Was Contact Attempted?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:41:04 |

US3532002

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '22 Sep 2020' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:41:04 |

US3532002

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                          | Time (GMT)           |
|--------------------------------------------|-------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:41:04 |



US3532002

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:41:04 |

US3532002

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:41:13 |

US3532002

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Oct 2020 17:41:13 |

US3532002

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Was Contact Attempted?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:41:43 |

US3532002

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '29 Sep 2020' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:41:43 |

US3532002

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                          | Time (GMT)           |
|--------------------------------------------|-------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:41:43 |

US3532002

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:41:43 |

US3532002

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:14

[Is the participant continuing to the next visit?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:41:49 |



US3532002

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Oct 2020 17:41:49 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:34:14**

[Was this visit performed?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:42:04 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '12 Oct 2020' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:42:04 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                          | User                          | Time (GMT)           |
|--------------------------------|-------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:42:04 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:34:14**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 12 Oct 2020 17:42:04 |

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:14

[Were vital signs assessed?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:43:12 |

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:14

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '12 Oct 2020' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:43:12 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                | User                          | Time (GMT)           |
|----------------------|-------------------------------|----------------------|
| User entered '12:33' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:43:12 |



US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Oct 2020 12:33' | System | 12 Oct 2020 17:43:12 |

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:14

Temperature (xxx.x)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered '97.6' F | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:43:12 |

US3532002

**Folder:** Visit 3 Day 57 (1)

**Form:** Vital Signs

**Generated On:** 26 Nov 2020 09:34:14

[Route of measurement](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'Oral (Oral)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:43:12 |

US3532002

**Folder:** Visit 3 Day 57 (1)

**Form:** Vital Signs

**Generated On:** 26 Nov 2020 09:34:14

[If Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:43:12 |

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:14

[Pulse \(xxx\)](#)

| Audit             | User                          | Time (GMT)           |
|-------------------|-------------------------------|----------------------|
| User entered '72' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:43:12 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 12 Oct 2020 17:43:12 |

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:14

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

| Audit             | User                          | Time (GMT)           |
|-------------------|-------------------------------|----------------------|
| User entered '20' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:43:12 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 12 Oct 2020 17:43:12 |



US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:14

Systolic Blood Pressure (xxx)

| Audit              | User                          | Time (GMT)           |
|--------------------|-------------------------------|----------------------|
| User entered '146' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:43:12 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 12 Oct 2020 17:43:12 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit             | User                          | Time (GMT)           |
|-------------------|-------------------------------|----------------------|
| User entered '86' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:43:12 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:34:14**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 12 Oct 2020 17:43:12 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:34:14**

[Was the physical examination performed?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:43:27 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:43:27 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:34:14**

[Was the sample collected?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:43:59 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered '12 Oct 2020' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:43:59 |



US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:34:14**

[Collection time \(00:00-23:59\)](#)

| Audit                | User                          | Time (GMT)           |
|----------------------|-------------------------------|----------------------|
| User entered '12:47' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:43:59 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:34:14**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '12 Oct 2020 12:47' | System | 12 Oct 2020 17:43:59 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 17:44:12 |

US3532002

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Oct 2020 17:44:12 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 64' | System | 11 Aug 2020 22:10:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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 (5546d99a3480aa1e)', Time: '2020-10-13T20:27:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '0ebc64bd-cd87-40f6-b82b-220d41e1230c' | System | 14 Oct 2020 00:27:58 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 14 Oct 2020 00:27:58 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

Have you been exposed to someone with 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 (5546d99a3480aa1e)', Time: '2020-10-13T20:27:48', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '0ebc64bd-cd87-40f6-b82b-220d41e1230c' | System | 14 Oct 2020 00:27:58 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 14 Oct 2020 00:27:58 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-10-13T20:27:53', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '0ebc64bd-cd87-40f6-b82b-220d41e1230c' | System | 14 Oct 2020 00:27:58 |
| User entered '13 Oct 2020 20:27:53'                                                                                                                                                                                                        | System | 14 Oct 2020 00:27:58 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 11 Aug 2020 22:10:10 |
| User entered '11 Oct 2020 00:01' | System | 11 Aug 2020 22:10:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 11 Aug 2020 22:10:10 |
| User entered '15 Oct 2020 23:59' | System | 11 Aug 2020 22:10:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 71' | System | 11 Aug 2020 22:10:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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 (5546d99a3480aa1e)', Time: '2020-10-18T00:02:08', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '49c44d92-382c-4216-a248-e3a3569473f3' | System | 18 Oct 2020 04:02:24 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 18 Oct 2020 04:02:24 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

Have you been exposed to someone with 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 (5546d99a3480aa1e)', Time: '2020-10-18T00:02:14', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '49c44d92-382c-4216-a248-e3a3569473f3' | System | 18 Oct 2020 04:02:24 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 18 Oct 2020 04:02:24 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-10-18T00:02:18', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '49c44d92-382c-4216-a248-e3a3569473f3' | System | 18 Oct 2020 04:02:24 |
| User entered '18 Oct 2020 00:02:18'                                                                                                                                                                                                        | System | 18 Oct 2020 04:02:24 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 11 Aug 2020 22:10:10 |
| User entered '18 Oct 2020 00:01' | System | 11 Aug 2020 22:10:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 11 Aug 2020 22:10:10 |
| User entered '22 Oct 2020 23:59' | System | 11 Aug 2020 22:10:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 78' | System | 11 Aug 2020 22:10:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[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 (e4a121161252b7b0)', Time: '2020-10-26T14:15:40', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a0bfe567-f6e3-42d9-9622-1a51262600e7' | System | 26 Oct 2020 18:15:51 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 26 Oct 2020 18:15:51 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2020-10-26T14:15:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a0bfe567-f6e3-42d9-9622-1a51262600e7' | System | 26 Oct 2020 18:15:51 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 26 Oct 2020 18:15:51 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-10-26T14:15:48', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a0bfe567-f6e3-42d9-9622-1a51262600e7' | System | 26 Oct 2020 18:15:51 |
| User entered '26 Oct 2020 14:15:48'                                                                                                                                                                                                        | System | 26 Oct 2020 18:15:51 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 11 Aug 2020 22:10:10 |
| User entered '25 Oct 2020 00:01' | System | 11 Aug 2020 22:10:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 11 Aug 2020 22:10:10 |
| User entered '29 Oct 2020 23:59' | System | 11 Aug 2020 22:10:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 92' | System | 11 Aug 2020 22:10:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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 (e4a121161252b7b0)', Time: '2020-11-08T15:16:25', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1f88b0a6-bb8b-474a-a9b2-9cfdefae4b6b' | System | 08 Nov 2020 20:16:38 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 08 Nov 2020 20:16:38 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2020-11-08T15:16:29', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1f88b0a6-bb8b-474a-a9b2-9cfdefae4b6b' | System | 08 Nov 2020 20:16:38 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 08 Nov 2020 20:16:38 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-11-08T15:16:35', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1f88b0a6-bb8b-474a-a9b2-9cfdefae4b6b' | System | 08 Nov 2020 20:16:38 |
| User entered '08 Nov 2020 15:16:35'                                                                                                                                                                                                        | System | 08 Nov 2020 20:16:38 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 11 Aug 2020 22:10:10 |
| User entered '08 Nov 2020 00:01' | System | 11 Aug 2020 22:10:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 11 Aug 2020 22:10:10 |
| User entered '12 Nov 2020 23:59' | System | 11 Aug 2020 22:10:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 11 Aug 2020 22:10:10 |
| User entered 'Day 99' | System | 11 Aug 2020 22:10:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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 (e4a121161252b7b0)', Time: '2020-11-15T18:52:54', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a2c71669-632f-424c-9449-d74d26e98160' | System | 15 Nov 2020 23:53:09 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 15 Nov 2020 23:53:09 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2020-11-15T18:52:58', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a2c71669-632f-424c-9449-d74d26e98160' | System | 15 Nov 2020 23:53:09 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 15 Nov 2020 23:53:09 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-11-15T18:53:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a2c71669-632f-424c-9449-d74d26e98160' | System | 15 Nov 2020 23:53:09 |
| User entered '15 Nov 2020 18:53:04'                                                                                                                                                                                                        | System | 15 Nov 2020 23:53:09 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 11 Aug 2020 22:10:10 |
| User entered '15 Nov 2020 00:01' | System | 11 Aug 2020 22:10:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 11 Aug 2020 22:10:10 |
| User entered '19 Nov 2020 23:59' | System | 11 Aug 2020 22:10:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 61' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '08 Oct 2020 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '12 Oct 2020 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 68' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '15 Oct 2020 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '19 Oct 2020 23:59' | System | 19 Nov 2020 04:09:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 75' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '22 Oct 2020 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '26 Oct 2020 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 82' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '29 Oct 2020 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '02 Nov 2020 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '05 Nov 2020 00:01' | System | 19 Nov 2020 04:09:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '09 Nov 2020 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '12 Nov 2020 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '16 Nov 2020 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

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 (e4a121161252b7b0)', Time: '2020-11-19T18:58:56', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '275bd0af-68e8-4293-b1bb-03dba9dcdf98' | System | 20 Nov 2020 00:59:09 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 20 Nov 2020 00:59:09 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2020-11-19T18:59:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '275bd0af-68e8-4293-b1bb-03dba9dcdf98' | System | 20 Nov 2020 00:59:09 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 20 Nov 2020 00:59:09 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-11-19T18:59:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '275bd0af-68e8-4293-b1bb-03dba9dcdf98' | System | 20 Nov 2020 00:59:09 |
| User entered '19 Nov 2020 18:59:04'                                                                                                                                                                                                        | System | 20 Nov 2020 00:59:09 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '19 Nov 2020 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '23 Nov 2020 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '26 Nov 2020 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '30 Nov 2020 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 09:34:14

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '03 Dec 2020 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '07 Dec 2020 23:59' | System | 19 Nov 2020 04:09:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '10 Dec 2020 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '14 Dec 2020 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '17 Dec 2020 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '21 Dec 2020 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '24 Dec 2020 00:01' | System | 19 Nov 2020 04:09:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '28 Dec 2020 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '31 Dec 2020 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '04 Jan 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '07 Jan 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '11 Jan 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 04:09:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '14 Jan 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '18 Jan 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '21 Jan 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '25 Jan 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '28 Jan 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '01 Feb 2021 23:59' | System | 19 Nov 2020 04:09:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '04 Feb 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '08 Feb 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '11 Feb 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '15 Feb 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '18 Feb 2021 00:01' | System | 19 Nov 2020 04:09:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '22 Feb 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '25 Feb 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '01 Mar 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '04 Mar 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '08 Mar 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 04:09:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '11 Mar 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '15 Mar 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:14

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '18 Mar 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '22 Mar 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '25 Mar 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '29 Mar 2021 23:59' | System | 19 Nov 2020 04:09:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '01 Apr 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '05 Apr 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '08 Apr 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '12 Apr 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '15 Apr 2021 00:01' | System | 19 Nov 2020 04:09:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '19 Apr 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '22 Apr 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '26 Apr 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '29 Apr 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '03 May 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 04:09:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '06 May 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '10 May 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '13 May 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '17 May 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '20 May 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '24 May 2021 23:59' | System | 19 Nov 2020 04:09:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '27 May 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '31 May 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '03 Jun 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '07 Jun 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '10 Jun 2021 00:01' | System | 19 Nov 2020 04:09:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '14 Jun 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '17 Jun 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '21 Jun 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '24 Jun 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '28 Jun 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 04:09:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '01 Jul 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '05 Jul 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '08 Jul 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '12 Jul 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '15 Jul 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '19 Jul 2021 23:59' | System | 19 Nov 2020 04:09:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '22 Jul 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '26 Jul 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '29 Jul 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '02 Aug 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 04:09:10 |

US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '05 Aug 2021 00:01' | System | 19 Nov 2020 04:09:10 |



US3532002

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '09 Aug 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '12 Aug 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '16 Aug 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '19 Aug 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '23 Aug 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '26 Aug 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '30 Aug 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '02 Sep 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '06 Sep 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '09 Sep 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '13 Sep 2021 23:59' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '16 Sep 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '20 Sep 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '23 Sep 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '27 Sep 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '30 Sep 2021 00:01' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '04 Oct 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '07 Oct 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '11 Oct 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '14 Oct 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '18 Oct 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '21 Oct 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '25 Oct 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '28 Oct 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '01 Nov 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '04 Nov 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '08 Nov 2021 23:59' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '11 Nov 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '15 Nov 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '18 Nov 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '22 Nov 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '25 Nov 2021 00:01' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '29 Nov 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '02 Dec 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '06 Dec 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '09 Dec 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '13 Dec 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '16 Dec 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '20 Dec 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '23 Dec 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '27 Dec 2021 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '30 Dec 2021 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '03 Jan 2022 23:59' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '06 Jan 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '10 Jan 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '13 Jan 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '17 Jan 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '20 Jan 2022 00:01' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '24 Jan 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '27 Jan 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '31 Jan 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '03 Feb 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '07 Feb 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '10 Feb 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '14 Feb 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '17 Feb 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '21 Feb 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '24 Feb 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '28 Feb 2022 23:59' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '03 Mar 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '07 Mar 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '10 Mar 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '14 Mar 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '17 Mar 2022 00:01' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '21 Mar 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '24 Mar 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '28 Mar 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '31 Mar 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '04 Apr 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '07 Apr 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '11 Apr 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '14 Apr 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '18 Apr 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '21 Apr 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '25 Apr 2022 23:59' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '28 Apr 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '02 May 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '05 May 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '09 May 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '12 May 2022 00:01' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '16 May 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '19 May 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '23 May 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '26 May 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '30 May 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '02 Jun 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '06 Jun 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '09 Jun 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '13 Jun 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '16 Jun 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '20 Jun 2022 23:59' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '23 Jun 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '27 Jun 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '30 Jun 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '04 Jul 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '07 Jul 2022 00:01' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '11 Jul 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '14 Jul 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '18 Jul 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '21 Jul 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '25 Jul 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '28 Jul 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '01 Aug 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '04 Aug 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '08 Aug 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '11 Aug 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '15 Aug 2022 23:59' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '18 Aug 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '22 Aug 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '25 Aug 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '29 Aug 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '01 Sep 2022 00:01' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '05 Sep 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '08 Sep 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '12 Sep 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '15 Sep 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '19 Sep 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '22 Sep 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '26 Sep 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '29 Sep 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '03 Oct 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '06 Oct 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '10 Oct 2022 23:59' | System | 19 Nov 2020 04:09:10 |



US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '13 Oct 2022 00:01' | System | 19 Nov 2020 04:09:10 |

US3532002

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:34:14**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 04:09:10 |
| Amendment Manager: User entered '17 Oct 2022 23:59' | System | 19 Nov 2020 04:09:10 |

US3532002

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:14

[Was Contact Attempted?](#)

| Audit                                                                                                                                                                                                           | User                | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                      | (b) (4), (b) (6)    | 03 Nov 2020 06:47:01 |
| User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System). | System              | 02 Nov 2020 21:11:54 |
| User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System). | System              | 02 Nov 2020 21:11:45 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                                                                                                                                                      | Etza Peters (b) (4) | 02 Nov 2020 21:11:45 |
| Query 'Data is required. Please complete.' answered with 'error' (Site from System).                                                                                                                            | Etza Peters (b) (4) | 30 Oct 2020 16:35:34 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                                                      | System              | 30 Oct 2020 16:35:25 |
| User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System). | System              | 30 Oct 2020 16:35:25 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                          | Etza Peters (b) (4) | 30 Oct 2020 16:35:25 |
| User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System). | System              | 30 Oct 2020 16:28:59 |
| User entered 'Yes (Y)'                                                                                                                                                                                          | Etza Peters (b) (4) | 30 Oct 2020 16:28:59 |

US3532002

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:14

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                | User                | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User entered '2 Nov 2020' reason for change: Data Entry Error                                                                                                                                                                                        | Etza Peters (b) (4) | 02 Nov 2020 21:11:45 |
| User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).             | System              | 30 Oct 2020 16:35:25 |
| Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System). | System              | 30 Oct 2020 16:35:25 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                                                               | Etza Peters (b) (4) | 30 Oct 2020 16:35:25 |
| User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).             | System              | 30 Oct 2020 16:28:59 |
| User entered '30 Oct 2020'                                                                                                                                                                                                                           | Etza Peters (b) (4) | 30 Oct 2020 16:28:59 |

US3532002

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                | Time (GMT)           |
|--------------------------------------------|---------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Etza Peters (b) (4) | 02 Nov 2020 21:11:54 |
| reason for change: Data Entry Error        | (b) (4)             |                      |
| User entered empty.                        | Etza Peters (b) (4) | 30 Oct 2020 16:28:59 |
|                                            | (b) (4)             |                      |

US3532002

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:34:14**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 30 Oct 2020 16:28:59 |

US3532002

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 02 Nov 2020 21:11:59 |



US3532002

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:34:14**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Nov 2020 21:11:59 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events Summary

**Generated On:** 26 Nov 2020 09:34:14

[Did the participant experience any adverse events?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Laila Hussaini (b) (4)<br>(b) (4) | 14 Aug 2020 14:04:40 |

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:14

[Adverse event](#)

| 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: Back pain aggravated - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 02 Sep 2020 08:58:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                                                                                    | Coder Import (b) (4)<br>(b) (4) | 02 Sep 2020 08:58:40 |
| Data point term sent to Coder                                                                                                                                                                                                                                              | System                          | 01 Sep 2020 19:02:21 |
| User entered 'Worsening Back Pain'                                                                                                                                                                                                                                         | Etza Peters (b) (4)<br>(b) (4)  | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Was this a medically-attended AE?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:14

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                          | User                | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).    | (b) (4), (b) (6)    | 11 Sep 2020 18:36:55 |
| User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System). | System              | 08 Sep 2020 12:49:08 |
| User entered '20 Aug 2020'                                                                                                                                                                                                     | Etza Peters (b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Start time \(00:00-23:59\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |



US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Ongoing?](#)

| Audit                                                    | User                | Time (GMT)           |
|----------------------------------------------------------|---------------------|----------------------|
| User entered 'No (N)' reason for change: New Information | Etza Peters (b) (4) | 08 Sep 2020 12:27:36 |
| User entered 'Yes (Y)'                                   | Etza Peters (b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                         | User                | Time (GMT)           |
|---------------------------------------------------------------|---------------------|----------------------|
| User entered '5 Sep 2020' reason for change: Data Entry Error | Etza Peters (b) (4) | 08 Sep 2020 12:27:36 |
| User entered empty.                                           | Etza Peters (b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[End time \(00:00-23:59\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Sep 2020 19:01:37 |

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:14

[Severity](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 03 Sep 2020 11:56:47 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 03 Sep 2020 11:56:47 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error | Etza Peters (b) (4) | 03 Sep 2020 11:56:47 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 01 Sep 2020 19:01:37 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 01 Sep 2020 19:01:37 |

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:14

[Is the adverse event serious?](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 03 Sep 2020 11:56:47 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 03 Sep 2020 11:56:47 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Etza Peters (b) (4) | 03 Sep 2020 11:56:47 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 01 Sep 2020 19:01:37 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Death](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |



US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Life threatening](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Admitted to ICU?](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Number of Days in ICU](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Persistent or significant disability or incapacity](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Congenital anomaly or birth defect](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |



US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Other medically important event](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:14

[Relationship to investigational product](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 03 Sep 2020 11:56:47 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 03 Sep 2020 11:56:47 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | Etza Peters (b) (4) | 03 Sep 2020 11:56:47 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 01 Sep 2020 19:01:37 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Relationship to Study Procedure](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 03 Sep 2020 11:56:47 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 03 Sep 2020 11:56:47 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | Etza Peters (b) (4) | 03 Sep 2020 11:56:47 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 01 Sep 2020 19:01:37 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 01 Sep 2020 19:01:37 |

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:14

[Action taken with investigational product](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 03 Sep 2020 11:56:47 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 03 Sep 2020 11:56:47 |
| User entered 'None (NONE)' reason for change: Data Entry Error                         | Etza Peters (b) (4) | 03 Sep 2020 11:56:47 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 01 Sep 2020 19:01:37 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[None](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Concomitant Medication](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '1' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Concomitant Procedure](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Outcome](#)

| Audit                                                                                      | User                | Time (GMT)           |
|--------------------------------------------------------------------------------------------|---------------------|----------------------|
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Etza Peters (b) (4) | 08 Sep 2020 12:27:36 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'                                 | Etza Peters (b) (4) | 01 Sep 2020 19:01:37 |



US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Narrative](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 19:01:37 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 03 Sep 2020 11:56:47 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:34:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 01 Sep 2020 19:01:37 |

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:14

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 23 Sep 2020 12:31:29 |
| User entered<br>'USA-US077-2020-mRNA-1273-P301000003' | System           | 23 Sep 2020 12:31:18 |
| User entered 'New'                                    | (b) (4), (b) (6) | 23 Sep 2020 12:31:18 |

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:14

[Adverse event](#)

| 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: Back pain aggravated - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 15 Sep 2020 23:42:53 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                                                               | Coder Import (b) (4)<br>(b) (4) | 15 Sep 2020 23:42:53 |
| Data point term sent to Coder                                                                                                                                                                                                                                              | System                          | 15 Sep 2020 23:42:13 |
| User entered 'Worsening Back Pain'                                                                                                                                                                                                                                         | Etza Peters (b) (4)<br>(b) (4)  | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Was this a medically-attended AE?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:41:17 |



US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| User entered '8 Sep 2020' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:41:17 |

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:14

Start time (00:00-23:59)

| Audit                                                                                                                                                                                                                                                    | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Per CDM: As per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. Enter the start time of the adverse event 24-hour clock format (HH:MM)'. Thank you.' (Site from DM).             | (b) (4), (b) (6)    | 24 Sep 2020 09:39:53 |
| Query 'Per CDM: As per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. Enter the start time of the adverse event 24-hour clock format (HH:MM)'. Thank you.' answered with 'unknown' (Site from DM). | Etza Peters (b) (4) | 22 Sep 2020 21:05:03 |
| User opened query 'Per CDM: As per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. Enter the start time of the adverse event 24-hour clock format (HH:MM)'. Thank you.' (Site from DM).             | (b) (4), (b) (6)    | 17 Sep 2020 07:28:36 |
| User closed query 'Data is required. Please provide.' (Site from System).                                                                                                                                                                                | (b) (4), (b) (6)    | 17 Sep 2020 07:28:03 |
| Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).                                                                                                                                                                    | Etza Peters (b) (4) | 15 Sep 2020 23:42:08 |
| User opened query 'Data is required. Please provide.' (Site from System).                                                                                                                                                                                | System              | 15 Sep 2020 23:41:17 |
| User entered empty.                                                                                                                                                                                                                                      | Etza Peters (b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 15 Sep 2020 23:41:17 |

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:14

[Ongoing?](#)

| Audit                                                     | User                | Time (GMT)           |
|-----------------------------------------------------------|---------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | Etza Peters (b) (4) | 02 Nov 2020 21:13:25 |
| User entered 'Yes (Y)'                                    | Etza Peters (b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

If not Ongoing, end date (*dd MMM yyyy*)

| Audit                                                          | User                | Time (GMT)           |
|----------------------------------------------------------------|---------------------|----------------------|
| User entered '14 Oct 2020' reason for change: Data Entry Error | Etza Peters (b) (4) | 02 Nov 2020 21:13:25 |
| User entered empty.                                            | Etza Peters (b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[End time \(00:00-23:59\)](#)

| Audit                                                                                 | User                | Time (GMT)           |
|---------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).             | (b) (4), (b) (6)    | 03 Nov 2020 06:46:35 |
| Query 'Data is required. Please provide.' answered with 'unknown' (Site from System). | Etza Peters (b) (4) | 02 Nov 2020 21:13:51 |
| User opened query 'Data is required. Please provide.' (Site from System).             | (b) (4)             | 02 Nov 2020 21:13:25 |
| User entered empty.                                                                   | System              | 02 Nov 2020 21:13:25 |
|                                                                                       | Etza Peters (b) (4) | 15 Sep 2020 23:41:17 |
|                                                                                       | (b) (4)             |                      |

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:14

[AE End Date and Time \(derived\)](#)

| Audit                                                                                                                                                                                                       | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).    | (b) (4), (b) (6) | 06 Nov 2020 14:36:47 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 02 Oct 2020 15:35:36 |
| User entered empty.                                                                                                                                                                                         | System           | 15 Sep 2020 23:41:17 |



US3532002

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Severity](#)

| Audit                                                                | User                | Time (GMT)           |
|----------------------------------------------------------------------|---------------------|----------------------|
| User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error | Etza Peters (b) (4) | 22 Sep 2020 22:20:20 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)'                   | Etza Peters (b) (4) | 15 Sep 2020 23:41:17 |

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:14

[Is the adverse event serious?](#)

| Audit                                                      | User                | Time (GMT)           |
|------------------------------------------------------------|---------------------|----------------------|
| User entered 'Yes (Y)' reason for change: Data Entry Error | Etza Peters (b) (4) | 22 Sep 2020 21:07:27 |
| User entered 'No (N)'                                      | Etza Peters (b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Death](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Life threatening](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                                                | User                                      | Time (GMT)           |
|------------------------------------------------------|-------------------------------------------|----------------------|
| User entered '1' reason for change: Data Entry Error | Etza Peters (b) (4)                       | 22 Sep 2020 21:07:27 |
| User entered '0'                                     | (b) (4)<br>Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit                                                          | User                | Time (GMT)           |
|----------------------------------------------------------------|---------------------|----------------------|
| User entered '16 Sep 2020' reason for change: Data Entry Error | Etza Peters (b) (4) | 22 Sep 2020 21:07:27 |
| User entered empty.                                            | Etza Peters (b) (4) | 15 Sep 2020 23:41:17 |

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:14

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit                                                          | User                | Time (GMT)           |
|----------------------------------------------------------------|---------------------|----------------------|
| User entered '18 Sep 2020' reason for change: Data Entry Error | Etza Peters (b) (4) | 22 Sep 2020 21:07:27 |
| User entered empty.                                            | Etza Peters (b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Admitted to ICU?](#)

| Audit                                                     | User                | Time (GMT)           |
|-----------------------------------------------------------|---------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | Etza Peters (b) (4) | 22 Sep 2020 21:07:27 |
| User entered empty.                                       | Etza Peters (b) (4) | 15 Sep 2020 23:41:17 |



US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Number of Days in ICU](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Persistent or significant disability or incapacity](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Congenital anomaly or birth defect](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Other medically important event](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:41:17 |

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:14

[Relationship to investigational product](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 15 Sep 2020 23:43:00 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 15 Sep 2020 23:43:00 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | Etza Peters (b) (4) | 15 Sep 2020 23:43:00 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 15 Sep 2020 23:41:17 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 15 Sep 2020 23:41:17 |

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:14

[Relationship to Study Procedure](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 15 Sep 2020 23:43:00 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 15 Sep 2020 23:43:00 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | Etza Peters (b) (4) | 15 Sep 2020 23:43:00 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 15 Sep 2020 23:41:17 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Action taken with investigational product](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 15 Sep 2020 23:43:00 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 15 Sep 2020 23:43:00 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error     | Etza Peters (b) (4) | 15 Sep 2020 23:43:00 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 15 Sep 2020 23:41:17 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[None](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:41:17 |



US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Concomitant Medication](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '1' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Concomitant Procedure](#)

| Audit                                                | User                                      | Time (GMT)           |
|------------------------------------------------------|-------------------------------------------|----------------------|
| User entered '1' reason for change: Data Entry Error | Etza Peters (b) (4)                       | 22 Sep 2020 21:07:27 |
| User entered '0'                                     | (b) (4)<br>Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:41:17 |

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:14

[Outcome](#)

| Audit                                                                                                                                                                                                                                                      | User                   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).                   | (b) (4), (b) (6)       | 03 Nov 2020 13:15:56 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).       | Etza Peters (b) (4)    | 02 Nov 2020 21:13:35 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error                                                                                                                                                                 | (b) (4)                | 02 Nov 2020 21:13:25 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error                                                                                                                                                             | Kathy Stephens (b) (4) | 28 Oct 2020 21:38:37 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).                   | (b) (4), (b) (6)       | 14 Oct 2020 20:10:51 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).                   | (b) (4), (b) (6)       | 14 Oct 2020 15:48:51 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'still ongoing' (Site from Safety). | Etza Peters (b) (4)    | 13 Oct 2020 15:19:53 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).                   | (b) (4), (b) (6)       | 02 Oct 2020 15:37:22 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'                                                                                                                                                                                     | Etza Peters (b) (4)    | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:41:17 |

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:14

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'PV Query: Was the subject tested for COVID-19 while hospitalized? If yes, please provide results. Please leave query open until information was received.' (Site from Safety).                                                                                                                    | (b) (4), (b) (6)    | 03 Nov 2020 13:15:58 |
| Query 'PV Query: Was the subject tested for COVID-19 while hospitalized? If yes, please provide results. Please leave query open until information was received.' answered with 'did not see evidence of covid test in med records' (Site from Safety).                                                              | Etza Peters (b) (4) | 02 Nov 2020 21:12:56 |
| User opened query 'PV Query: Was the subject tested for COVID-19 while hospitalized? If yes, please provide results. Please leave query open until information was received.' (Site from Safety).                                                                                                                    | (b) (4), (b) (6)    | 29 Oct 2020 13:13:48 |
| User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.                                          | (b) (4), (b) (6)    | 26 Oct 2020 15:10:28 |
| ' (Site from Safety).                                                                                                                                                                                                                                                                                                |                     |                      |
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.                                                      | Etza Peters (b) (4) | 25 Oct 2020 19:51:11 |
| ' answered with 'Hospital Discharge summary sent on 23OCT2020' (Site from Safety).                                                                                                                                                                                                                                   | (b) (4)             |                      |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety). | (b) (4), (b) (6)    | 21 Oct 2020 21:56:41 |
| User closed query 'PV Query: Was the subject tested for COVID-19 while hospitalized? If yes, please provide results.' (Site from Safety).                                                                                                                                                                            | (b) (4), (b) (6)    | 21 Oct 2020 21:56:38 |
| 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)    | 21 Oct 2020 21:56:33 |

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:14

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                       | User                           | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User closed query 'PV Query: Please confirm date of transforaminal lumbar interbody fusion.' (Site from Safety).                                                                                                                                                                                                                                            | (b) (4), (b) (6)               | 21 Oct 2020 21:56:30 |
| Query 'PV Query: Please confirm date of transforaminal lumbar interbody fusion.' answered with 'Waiting for med records to be sent' (Site from Safety).                                                                                                                                                                                                     | Etza Peters (b) (4)<br>(b) (4) | 20 Oct 2020 16:52:06 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'Waiting for med records to be sent' (Site from Safety). | Etza Peters (b) (4)<br>(b) (4) | 20 Oct 2020 16:52:02 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Waiting for med records to be sent' (Site from Safety).                                                                                                                                       | Etza Peters (b) (4)<br>(b) (4) | 20 Oct 2020 16:51:58 |
| Query 'PV Query: Was the subject tested for COVID-19 while hospitalized? If yes, please provide results.' answered with 'waiting for med records to be sent' (Site from Safety).                                                                                                                                                                            | Etza Peters (b) (4)<br>(b) (4) | 20 Oct 2020 16:51:40 |
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.<br>' (Site from Safety).                                                        | (b) (4), (b) (6)               | 02 Oct 2020 15:40:26 |
| User opened query 'PV Query: Please confirm date of transforaminal lumbar interbody fusion.' (Site from Safety).                                                                                                                                                                                                                                            | (b) (4), (b) (6)               | 02 Oct 2020 15:37:48 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).                                        | (b) (4), (b) (6)               | 02 Oct 2020 15:37:36 |

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:34:14

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                       | User                | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| 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)    | 02 Oct 2020 15:35:55 |
| User opened query 'PV Query: Was the subject tested for COVID-19 while hospitalized? If yes, please provide results.' (Site from Safety).                                                                                                                                                   | (b) (4), (b) (6)    | 02 Oct 2020 15:35:19 |
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).                                                                                                                                                                                     | System              | 22 Sep 2020 22:09:18 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).                                                                                                                                                                         | System              | 22 Sep 2020 22:09:18 |
| User entered 'Due to underlying back problems and unrelated to vaccine. He had a transforaminal lumbar interbody fusion of his spine due to degenerative disk disease in his back (an underlying medical history problem). Hospitalized after surgery.' reason for change: Data Entry Error | Etza Peters (b) (4) | 22 Sep 2020 22:09:18 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).                                                                                                                                                                                     | System              | 22 Sep 2020 21:07:27 |
| User entered empty.                                                                                                                                                                                                                                                                         | Etza Peters (b) (4) | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Sep 2020 21:07:27 |
| User entered '0' | System | 15 Sep 2020 23:41:17 |



US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Sep 2020 23:41:17 |

US3532002

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:34:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 22 Sep 2020 21:07:27 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 09:34:14**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:28:11 |

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:14

[Name of Medication](#)

| Audit                                                                                                                                                                                                         | User                                     | Time (GMT)                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------|
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: LIPID<br>MODIFYING AGENTS, ATC: LIPID MODIFYING<br>AGENTS, PLAIN, ATC: FIBRATES, PRODUCT:<br>FENOFIBRATE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)          | 14 Aug 2020 21:41:17                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.                                                                                                    | Coder Import (b) (4)<br>(b) (4)          | 14 Aug 2020 21:41:17                         |
| Data point term sent to Coder<br>Coding entries removed.                                                                                                                                                      | System<br>Etza Peters (b) (4)<br>(b) (4) | 14 Aug 2020 19:06:13<br>14 Aug 2020 19:06:08 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: LIPID<br>MODIFYING AGENTS, ATC: LIPID MODIFYING<br>AGENTS, PLAIN, ATC: FIBRATES, PRODUCT:<br>FENOFIBRATE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)          | 14 Aug 2020 00:20:12                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.                                                                                                    | Coder Import (b) (4)<br>(b) (4)          | 14 Aug 2020 00:20:12                         |
| Data point term sent to Coder<br>User entered 'Fenofibrate'                                                                                                                                                   | System<br>Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:30:19<br>11 Aug 2020 23:29:49 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:29:49 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Indication](#)

| Audit                                                                   | User                | Time (GMT)           |
|-------------------------------------------------------------------------|---------------------|----------------------|
| User entered 'ELEVATED CHOLESTERoL' reason for change: Data Entry Error | Etza Peters (b) (4) | 14 Aug 2020 19:06:08 |
| User entered 'Elevated Cholesterol'                                     | Etza Peters (b) (4) | 11 Aug 2020 23:29:49 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose per administration](#)

| Audit              | User                           | Time (GMT)           |
|--------------------|--------------------------------|----------------------|
| User entered '145' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:29:49 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'mg (mg)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:29:49 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

If dose unit is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:29:49 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Frequency](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'once daily (QD)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:29:49 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:29:49 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:29:49 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:29:49 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:29:49 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '1' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:29:49 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Ongoing?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:29:49 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:29:49 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:29:49 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 23:29:49 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 23:29:49 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 23:29:49 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                   | User                            | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: BETA<br>BLOCKING AGENTS, ATC: BETA BLOCKING<br>AGENTS, ATC: ALPHA AND BETA BLOCKING<br>AGENTS, PRODUCT: CARVEDILOL - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:17 |
| 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) | 11 Aug 2020 23:33:17 |
| Data point term sent to Coder                                                                                                                                                                                           | System                          | 11 Aug 2020 23:32:25 |
| User entered 'Carvedilol'                                                                                                                                                                                               | Etza Peters (b) (4)<br>(b) (4)  | 11 Aug 2020 23:32:25 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:32:25 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Indication](#)

| Audit                       | User                           | Time (GMT)           |
|-----------------------------|--------------------------------|----------------------|
| User entered 'Hypertension' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:32:25 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose per administration](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered '6.25' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:32:25 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'mg (mg)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:32:25 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

If dose unit is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:32:25 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Frequency](#)

| Audit                            | User                | Time (GMT)           |
|----------------------------------|---------------------|----------------------|
| User entered 'twice daily (BID)' | Etza Peters (b) (4) | 11 Aug 2020 23:32:25 |
|                                  | (b) (4)             |                      |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:32:25 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:32:25 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:32:25 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:32:25 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '1' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:32:25 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Ongoing?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:32:25 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:32:25 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:32:25 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 11 Aug 2020 23:32:25 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 23:32:25 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 23:32:25 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                     | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CALCIUM<br>CHANNEL BLOCKERS, ATC: SELECTIVE<br>CALCIUM CHANNEL BLOCKERS WITH<br>MAINLY VASCULAR EFFECTS, ATC:<br>DIHYDROPYRIDINE DERIVATIVES, PRODUCT:<br>AMLODIPINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 23:34:16 |
| 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) | 11 Aug 2020 23:34:16 |
| Data point term sent to Coder                                                                                                                                                                                                                                             | System                          | 11 Aug 2020 23:33:26 |
| User entered 'Amlodipine'                                                                                                                                                                                                                                                 | Etza Peters (b) (4)<br>(b) (4)  | 11 Aug 2020 23:33:23 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:23 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Indication](#)

| Audit                       | User                           | Time (GMT)           |
|-----------------------------|--------------------------------|----------------------|
| User entered 'Hypertension' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:23 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose per administration](#)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '10' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:23 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'mg (mg)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:23 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

If dose unit is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:23 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Frequency](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'once daily (QD)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:23 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:23 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:23 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:23 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:23 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '1' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:23 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Ongoing?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:23 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:23 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:23 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 23:33:23 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 23:33:23 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 23:33:23 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                          | User                            | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: AGENTS<br>ACTING ON THE RENIN-ANGIOTENSIN<br>SYSTEM, ATC: ANGIOTENSIN II RECEPTOR<br>BLOCKERS (ARBS), PLAIN, ATC:<br>ANGIOTENSIN II RECEPTOR BLOCKERS<br>(ARBS), PLAIN, PRODUCT: LOSARTAN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 23:35:17 |
| 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) | 11 Aug 2020 23:35:17 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                  | System                          | 11 Aug 2020 23:34:27 |
| User entered 'Losartan'                                                                                                                                                                                                                                                                        | Etza Peters (b) (4)<br>(b) (4)  | 11 Aug 2020 23:33:54 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:54 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Indication](#)

| Audit                       | User                           | Time (GMT)           |
|-----------------------------|--------------------------------|----------------------|
| User entered 'Hypertension' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:54 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose per administration](#)

| Audit              | User                           | Time (GMT)           |
|--------------------|--------------------------------|----------------------|
| User entered '100' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:54 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'mg (mg)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:54 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

If dose unit is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:54 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Frequency](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'once daily (QD)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:54 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:54 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:54 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:54 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:54 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '1' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:54 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Ongoing?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:54 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:33:54 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Was this medication taken for solicited event?](#)

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:50:04 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 11 Aug 2020 23:50:04 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Etza Peters (b) (4) | 11 Aug 2020 23:50:04 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 11 Aug 2020 23:33:54 |
| User entered empty.                                                                    | Etza Peters (b) (4) | 11 Aug 2020 23:33:54 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 23:33:54 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 23:33:54 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 23:33:54 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                      | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| 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: BABY ASPIRIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 22 Sep 2020 23:08:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                                                                                                                       | Coder Import (b) (4)<br>(b) (4) | 22 Sep 2020 23:08:40 |
| Data point term sent to Coder                                                                                                                                                                                                                                              | System                          | 22 Sep 2020 22:17:44 |
| Coding entries removed.                                                                                                                                                                                                                                                    | Etza Peters (b) (4)<br>(b) (4)  | 22 Sep 2020 22:17:29 |
| 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: BABY ASPIRIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 12 Aug 2020 10:35:21 |
| 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) | 12 Aug 2020 10:35:21 |
| Data point term sent to Coder                                                                                                                                                                                                                                              | System                          | 11 Aug 2020 23:36:32 |
| User entered 'Baby Aspirin'                                                                                                                                                                                                                                                | Etza Peters (b) (4)<br>(b) (4)  | 11 Aug 2020 23:35:38 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:35:38 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

[Indication](#)

| Audit                                                                                                                                                                                                                                                              | User                           | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User closed query 'Per DM CLR: Please review if this is related to MH=HYPERTENSION . If so, update indication so there is an appropriate match with MH condition. Else, confirm if used for heart health and update prophylaxis field.<br>' (Site from DM).        | (b) (4), (b) (6)               | 24 Sep 2020 09:55:10 |
| Query 'Per DM CLR: Please review if this is related to MH=HYPERTENSION . If so, update indication so there is an appropriate match with MH condition. Else, confirm if used for heart health and update prophylaxis field.<br>' answered with 'ok' (Site from DM). | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 22:17:33 |
| User entered 'GENERAL Heart HEALTH' reason for change: Data Entry Error                                                                                                                                                                                            | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 22:17:29 |
| User opened query 'Per DM CLR: Please review if this is related to MH=HYPERTENSION . If so, update indication so there is an appropriate match with MH condition. Else, confirm if used for heart health and update prophylaxis field.<br>' (Site from DM).        | (b) (4), (b) (6)               | 22 Sep 2020 06:14:01 |
| User entered 'General Health'                                                                                                                                                                                                                                      | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:35:38 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose per administration](#)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '81' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:35:38 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'mg (mg)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:35:38 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

If dose unit is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:35:38 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

[Frequency](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'once daily (QD)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:35:38 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:35:38 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:35:38 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:35:38 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date \(dd MMM yyyy\)](#)

| Audit                                                                                                                                                                                                                                                      | User                | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed 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). | (b) (4), (b) (6)    | 12 Aug 2020 10:54:31 |
| 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.'                                 | Etza Peters (b) (4) | 11 Aug 2020 23:50:48 |
| answered with 'Medication is ongoing' (Site from System).                                                                                                                                                                                                  | (b) (4)             |                      |
| 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              | 11 Aug 2020 23:35:38 |
| User entered 'un UNK 2016'                                                                                                                                                                                                                                 | Etza Peters (b) (4) | 11 Aug 2020 23:35:38 |
|                                                                                                                                                                                                                                                            | (b) (4)             |                      |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:35:38 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

[Ongoing?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:35:38 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:35:38 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:35:38 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 23:35:38 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 23:35:38 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 23:35:38 |

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:14

[Name of Medication](#)

| Audit                                                                                                                                                                                                                              | User                                     | Time (GMT)                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|----------------------------------------------|
| 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: ROSUVASTATIN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)          | 14 Aug 2020 20:44:46                         |
| 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)          | 14 Aug 2020 20:44:46                         |
| Data point term sent to Coder<br>Coding entries removed.                                                                                                                                                                           | System<br>Etza Peters (b) (4)<br>(b) (4) | 14 Aug 2020 19:07:18<br>14 Aug 2020 19:06:40 |
| 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: ROSUVASTATIN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)          | 12 Aug 2020 18:37:19                         |
| 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)          | 12 Aug 2020 18:37:19                         |
| Data point term sent to Coder<br>User entered 'Rosuvastatin'                                                                                                                                                                       | System<br>Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:38:34<br>11 Aug 2020 23:37:43 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:37:43 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

[Indication](#)

| Audit                                                                   | User                | Time (GMT)           |
|-------------------------------------------------------------------------|---------------------|----------------------|
| User entered 'ELEVATED CHOLESTERoL' reason for change: Data Entry Error | Etza Peters (b) (4) | 14 Aug 2020 19:06:40 |
| User entered 'Elevated Cholesterol'                                     | Etza Peters (b) (4) | 11 Aug 2020 23:37:43 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose per administration](#)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '20' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:37:43 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'mg (mg)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:37:43 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

If dose unit is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:37:43 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

[Frequency](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'once daily (QD)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:37:43 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:37:43 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:37:43 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:37:43 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:37:43 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '1' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:37:43 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

[Ongoing?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:37:43 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:37:43 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:37:43 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 23:37:43 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 23:37:43 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 23:37:43 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                             | User                 | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Aug 2020 23:40:22 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                         | Coder Import (b) (4) | 11 Aug 2020 23:40:22 |
| Data point term sent to Coder                                                                                                                                                                                                                                                     | System               | 11 Aug 2020 23:39:36 |
| User entered 'Ozempic'                                                                                                                                                                                                                                                            | Etza Peters (b) (4)  | 11 Aug 2020 23:38:59 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:38:59 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

[Indication](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'Type 2 Diabetes' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:38:59 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose per administration](#)

| Audit                                                                                                                                                                          | User                           | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User closed query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose. Reconcile and update as appropriate. ' (Site from DM).              | (b) (4), (b) (6)               | 24 Sep 2020 09:58:43 |
| Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose. Reconcile and update as appropriate. ' answered with 'reviewed' (Site from DM). | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 22:16:15 |
| User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose. Reconcile and update as appropriate. ' (Site from DM).              | (b) (4), (b) (6)               | 22 Sep 2020 06:17:42 |
| User entered '5'                                                                                                                                                               | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:38:59 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'mg (mg)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:38:59 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

If dose unit is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:38:59 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

[Frequency](#)

| Audit                                             | User                | Time (GMT)           |
|---------------------------------------------------|---------------------|----------------------|
| User entered 'every week (QS)' reason for change: | Etza Peters (b) (4) | 28 Aug 2020 14:44:40 |
| Data Entry Error                                  | (b) (4)             |                      |
| User entered 'other (OTHER)'                      | Etza Peters (b) (4) | 11 Aug 2020 23:38:59 |
|                                                   | (b) (4)             |                      |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

If frequency is Other, specify

| Audit                                                                                                                                                                           | User                | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Per CDM: Every week option is available at drop down at frequency field. Please verify and consider to update CRF else clarify.' (Site from DM).             | (b) (4), (b) (6)    | 31 Aug 2020 15:50:16 |
| Query 'Per CDM: Every week option is available at drop down at frequency field. Please verify and consider to update CRF else clarify.' answered with 'updated' (Site from DM). | Etza Peters (b) (4) | 28 Aug 2020 14:44:50 |
| User entered empty; reason for change Data Entry Error                                                                                                                          | (b) (4)             | 28 Aug 2020 14:44:40 |
| User opened query 'Per CDM: Every week option is available at drop down at frequency field. Please verify and consider to update CRF else clarify.' (Site from DM).             | (b) (4), (b) (6)    | 28 Aug 2020 11:32:31 |
| User entered 'weekly'                                                                                                                                                           | Etza Peters (b) (4) | 11 Aug 2020 23:38:59 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

[Route of administration](#)

| Audit                                      | User                           | Time (GMT)           |
|--------------------------------------------|--------------------------------|----------------------|
| User entered 'Subcutaneous (SUBCUTANEOUS)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:38:59 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:38:59 |

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:14

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                      | User                | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed 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). | (b) (4), (b) (6)    | 12 Aug 2020 10:54:47 |
| 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.'                                 | Etza Peters (b) (4) | 11 Aug 2020 23:51:40 |
| answered with 'Medication is ongoing' (Site from System).                                                                                                                                                                                                  | (b) (4)             |                      |
| 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              | 11 Aug 2020 23:38:59 |
| User entered 'un UNK 2019'                                                                                                                                                                                                                                 | Etza Peters (b) (4) | 11 Aug 2020 23:38:59 |
|                                                                                                                                                                                                                                                            | (b) (4)             |                      |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:38:59 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

[Ongoing?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:38:59 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:38:59 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:38:59 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1'    | System | 28 Aug 2020 14:44:40 |
| User entered empty. | System | 11 Aug 2020 23:38:59 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1'    | System | 28 Aug 2020 14:44:40 |
| User entered empty. | System | 11 Aug 2020 23:38:59 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '803 (803)' | System | 28 Aug 2020 14:44:40 |
| User entered empty.      | System | 11 Aug 2020 23:38:59 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                   | User                 | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| 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) | 11 Aug 2020 23:41:16 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                               | Coder Import (b) (4) | 11 Aug 2020 23:41:16 |
| Data point term sent to Coder                                                                                                                                                                                           | System               | 11 Aug 2020 23:40:38 |
| User entered 'Metformin'                                                                                                                                                                                                | Etza Peters (b) (4)  | 11 Aug 2020 23:40:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:40:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

[Indication](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'Type 2 Diabetes' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:40:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose per administration](#)

| Audit              | User                           | Time (GMT)           |
|--------------------|--------------------------------|----------------------|
| User entered '750' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:40:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'mg (mg)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:40:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

If dose unit is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:40:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

[Frequency](#)

| Audit                            | User                           | Time (GMT)           |
|----------------------------------|--------------------------------|----------------------|
| User entered 'twice daily (BID)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:40:22 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:40:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:40:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:40:22 |

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:34:14

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                      | User                | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed 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). | (b) (4), (b) (6)    | 12 Aug 2020 10:54:59 |
| 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.'                                 | Etza Peters (b) (4) | 11 Aug 2020 23:51:52 |
| answered with 'Medication is ongoing' (Site from System).                                                                                                                                                                                                  | (b) (4)             |                      |
| 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              | 11 Aug 2020 23:40:22 |
| User entered 'un UNK 2016'                                                                                                                                                                                                                                 | Etza Peters (b) (4) | 11 Aug 2020 23:40:22 |
|                                                                                                                                                                                                                                                            | (b) (4)             |                      |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:40:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

[Ongoing?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:40:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:40:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:40:22 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 11 Aug 2020 23:40:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 23:40:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 23:40:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                              | User                 | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Aug 2020 23:42:16 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                          | Coder Import (b) (4) | 11 Aug 2020 23:42:16 |
| Data point term sent to Coder                                                                                                                                                                                                      | System               | 11 Aug 2020 23:41:42 |
| User entered 'Levothyroxine'                                                                                                                                                                                                       | Etza Peters (b) (4)  | 11 Aug 2020 23:41:27 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:41:27 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

[Indication](#)

| Audit                         | User                           | Time (GMT)           |
|-------------------------------|--------------------------------|----------------------|
| User entered 'Hypothyroidism' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:41:27 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose per administration](#)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| User entered '50' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:41:27 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose unit](#)

| Audit                                                      | User                | Time (GMT)           |
|------------------------------------------------------------|---------------------|----------------------|
| User entered 'ug (ug)' reason for change: Data Entry Error | Etza Peters (b) (4) | 21 Oct 2020 17:37:47 |
| User entered 'Other (OTHER)'                               | Etza Peters (b) (4) | 11 Aug 2020 23:41:27 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

[If dose unit is Other, specify](#)

| Audit                                                  | User                | Time (GMT)           |
|--------------------------------------------------------|---------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Etza Peters (b) (4) | 21 Oct 2020 17:37:47 |
| User entered 'mcg'                                     | Etza Peters (b) (4) | 11 Aug 2020 23:41:27 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

[Frequency](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'once daily (QD)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:41:27 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:41:27 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:41:27 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:41:27 |

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:34:14

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                      | User                | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed 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). | (b) (4), (b) (6)    | 12 Aug 2020 10:55:06 |
| 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.'                                 | Etza Peters (b) (4) | 11 Aug 2020 23:52:09 |
| answered with 'Medication is ongoing' (Site from System).                                                                                                                                                                                                  | (b) (4)             |                      |
| 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              | 11 Aug 2020 23:41:27 |
| User entered 'un UNK 1985'                                                                                                                                                                                                                                 | Etza Peters (b) (4) | 11 Aug 2020 23:41:27 |
|                                                                                                                                                                                                                                                            | (b) (4)             |                      |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:41:27 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

[Ongoing?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:41:27 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:41:27 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 11 Aug 2020 23:41:27 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 23:41:27 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 23:41:27 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 23:41:27 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                                                        | User                            | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STERIODS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: IBUPROFEN,<br>PRODUCTSYNONYM: ADVIL [IBUPROFEN] -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 15 Sep 2020 23:46:50 |
| 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) | 15 Sep 2020 23:46:50 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                | System                          | 15 Sep 2020 23:45:16 |
| User entered 'Advil'                                                                                                                                                                                                                                                                                                         | Etza Peters (b) (4)<br>(b) (4)  | 15 Sep 2020 23:44:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:44:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Indication](#)

| Audit                   | User                           | Time (GMT)           |
|-------------------------|--------------------------------|----------------------|
| User entered 'Headache' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:44:22 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose per administration](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'unknown' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:44:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose unit](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'mg (mg)' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:44:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

If dose unit is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:44:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Frequency](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'once (ONCE)' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:44:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:44:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:44:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:44:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '10 Sep 2020' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:44:22 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:44:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Ongoing?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:44:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '10 Sep 2020' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:44:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Was this medication taken for solicited event?](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | User                          | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|----------------------|
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.<br>' (Site from DM).                               | (b) (4), (b) (6)              | 14 Oct 2020 04:03:38 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.<br>' answered with 'did not meet AE reporting' (Site from DM). | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 18:22:17 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.<br>' (Site from DM).                               | (b) (4), (b) (6)              | 02 Oct 2020 11:59:42 |
| v6.020 DTW (1102)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                               | 1867 of 2036         |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Was this medication taken for solicited event?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 15 Sep 2020 23:44:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 15 Sep 2020 23:44:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 15 Sep 2020 23:44:22 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 15 Sep 2020 23:44:22 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                  | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE<br>RELAXANTS, ATC: MUSCLE RELAXANTS,<br>CENTRALLY ACTING AGENTS, ATC:<br>CARBAMIC ACID ESTERS, PRODUCT:<br>METHOCARBAMOL - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 02 Sep 2020 03:20:35 |
| 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) | 02 Sep 2020 03:20:35 |
| Data point term sent to Coder                                                                                                                                                                                                          | System                          | 01 Sep 2020 18:57:07 |
| User entered 'methocarbamol'                                                                                                                                                                                                           | Etza Peters (b) (4)<br>(b) (4)  | 01 Sep 2020 18:56:26 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:56:26 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

[Indication](#)

| Audit                              | User                           | Time (GMT)           |
|------------------------------------|--------------------------------|----------------------|
| User entered 'Worsening back pain' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:56:26 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose per administration](#)

| Audit              | User                           | Time (GMT)           |
|--------------------|--------------------------------|----------------------|
| User entered '500' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:56:26 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose unit](#)

| Audit                  | User                | Time (GMT)           |
|------------------------|---------------------|----------------------|
| User entered 'mg (mg)' | Etza Peters (b) (4) | 01 Sep 2020 18:56:26 |
|                        | (b) (4)             |                      |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

If dose unit is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:56:26 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

[Frequency](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| User entered 'as needed (PRN)' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:56:26 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

[If frequency is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:56:26 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:56:26 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:56:26 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'un Aug 2020' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:56:26 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:56:26 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

[Ongoing?](#)

| Audit                                                     | User                | Time (GMT)           |
|-----------------------------------------------------------|---------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | Etza Peters (b) (4) | 02 Nov 2020 21:26:49 |
| User entered 'Yes (Y)'                                    | Etza Peters (b) (4) | 01 Sep 2020 18:56:26 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                                                          | User                | Time (GMT)           |
|----------------------------------------------------------------|---------------------|----------------------|
| User entered '14 Oct 2020' reason for change: Data Entry Error | Etza Peters (b) (4) | 02 Nov 2020 21:26:49 |
| User entered empty.                                            | Etza Peters (b) (4) | 01 Sep 2020 18:56:26 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 01 Sep 2020 18:56:26 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Sep 2020 18:56:26 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Sep 2020 18:56:26 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Sep 2020 18:56:26 |

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:14

[Name of Medication](#)

| Audit                                                                                                                                                                                                    | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 23 Sep 2020 09:42:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                                                     | Coder Import (b) (4)<br>(b) (4) | 23 Sep 2020 09:42:46 |
| Data point term sent to Coder                                                                                                                                                                            | System                          | 22 Sep 2020 22:15:35 |
| User entered 'Percocet'                                                                                                                                                                                  | Etza Peters (b) (4)<br>(b) (4)  | 22 Sep 2020 22:15:17 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:34:14**

[Prophylaxis](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 22:15:17 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:34:14**

[Indication](#)

| Audit                              | User                           | Time (GMT)           |
|------------------------------------|--------------------------------|----------------------|
| User entered 'Worsening Back Pain' | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 22:15:17 |

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:34:14

[Dose per administration](#)

| Audit                                                                                                                                                                                                                                         | User                           | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User closed query 'Per DM CLR: Please provide the dosage for this combination medication as there are many dosage options for this drug (e.g., 5/325 mg, 10/325 mg, etc). Update ConMed eCRF as appropriate.<br>' (Site from DM).             | (b) (4), (b) (6)               | 27 Oct 2020 07:48:52 |
| Query 'Per DM CLR: Please provide the dosage for this combination medication as there are many dosage options for this drug (e.g., 5/325 mg, 10/325 mg, etc). Update ConMed eCRF as appropriate.<br>' answered with 'updated' (Site from DM). | Etza Peters (b) (4)<br>(b) (4) | 23 Oct 2020 17:26:28 |
| User entered '10/325' reason for change: Data Entry Error                                                                                                                                                                                     | Etza Peters (b) (4)<br>(b) (4) | 23 Oct 2020 17:26:00 |
| User opened query 'Per DM CLR: Please provide the dosage for this combination medication as there are many dosage options for this drug (e.g., 5/325 mg, 10/325 mg, etc). Update ConMed eCRF as appropriate.<br>' (Site from DM).             | (b) (4), (b) (6)               | 23 Oct 2020 06:51:22 |
| User entered '1'                                                                                                                                                                                                                              | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 22:15:17 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose unit](#)

| Audit                                                      | User                | Time (GMT)           |
|------------------------------------------------------------|---------------------|----------------------|
| User entered 'mg (mg)' reason for change: Data Entry Error | Etza Peters (b) (4) | 23 Oct 2020 17:26:00 |
| User entered 'tablet (TABLET)'                             | Etza Peters (b) (4) | 22 Sep 2020 22:15:17 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:34:14**

If dose unit is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 22:15:17 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:34:14**

[Frequency](#)

| Audit                        | User                           | Time (GMT)           |
|------------------------------|--------------------------------|----------------------|
| User entered 'other (OTHER)' | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 22:15:17 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:34:14**

[If frequency is Other, specify](#)

| Audit                        | User                           | Time (GMT)           |
|------------------------------|--------------------------------|----------------------|
| User entered 'Every 6 hours' | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 22:15:17 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:34:14**

[Route of administration](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 22:15:17 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:34:14**

If route of administration is Other, specify

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 22:15:17 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                | Time (GMT)           |
|----------------------------|---------------------|----------------------|
| User entered '17 Sep 2020' | Etza Peters (b) (4) | 22 Sep 2020 22:15:17 |
|                            | (b) (4)             |                      |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                           | Time (GMT)           |
|------------------|--------------------------------|----------------------|
| User entered '0' | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 22:15:17 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:34:14**

[Ongoing?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 22:15:17 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:34:14**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 22:15:17 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:34:14**

[Was this medication taken for solicited event?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 22:15:17 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:34:14**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Sep 2020 22:15:17 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Sep 2020 22:15:17 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Sep 2020 22:15:17 |

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:34:14

[Name of Medication](#)

| Audit                                                                                                                                                                                       | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 05 Nov 2020 13:41:20 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                   | Coder Import (b) (4)<br>(b) (4) | 05 Nov 2020 13:41:20 |
| Data point term sent to Coder                                                                                                                                                               | System                          | 02 Nov 2020 21:18:08 |
| Coding entries removed.                                                                                                                                                                     | Etza Peters (b) (4)<br>(b) (4)  | 02 Nov 2020 21:17:35 |
| Coding entries removed.                                                                                                                                                                     | Etza Peters (b) (4)<br>(b) (4)  | 02 Nov 2020 21:17:35 |
| User entered 'INFLUENZA VACCINE' reason for change: Data Entry Error                                                                                                                        | Etza Peters (b) (4)<br>(b) (4)  | 02 Nov 2020 21:17:35 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 12 Oct 2020 21:20:27 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                                        | Coder Import (b) (4)<br>(b) (4) | 12 Oct 2020 21:20:27 |
| Data point term sent to Coder                                                                                                                                                               | System                          | 12 Oct 2020 18:21:55 |
| User entered 'high dose influenza vaccine'                                                                                                                                                  | Lisa Macoy (b) (4)<br>(b) (4)   | 12 Oct 2020 18:21:24 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

[Prophylaxis](#)

| Audit                  | User                          | Time (GMT)           |
|------------------------|-------------------------------|----------------------|
| User entered 'Yes (Y)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 18:21:24 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

[Indication](#)

| Audit                                            | User                | Time (GMT)           |
|--------------------------------------------------|---------------------|----------------------|
| User entered 'Annual Vaccine' reason for change: | Etza Peters (b) (4) | 02 Nov 2020 21:17:35 |
| Data Entry Error                                 | (b) (4)             |                      |
| User entered 'influenza'                         | Lisa Macoy (b) (4)  | 12 Oct 2020 18:21:24 |
|                                                  | (b) (4)             |                      |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose per administration](#)

| Audit                                                      | User                | Time (GMT)           |
|------------------------------------------------------------|---------------------|----------------------|
| User entered 'unknown' reason for change: Data Entry Error | Etza Peters (b) (4) | 02 Nov 2020 21:17:35 |
| User entered '0.5'                                         | Lisa Macoy (b) (4)  | 12 Oct 2020 18:21:24 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

[Dose unit](#)

| Audit                                                               | User                           | Time (GMT)           |
|---------------------------------------------------------------------|--------------------------------|----------------------|
| User entered 'Other (OTHER)' reason for change:<br>Data Entry Error | Etza Peters (b) (4)<br>(b) (4) | 02 Nov 2020 21:17:35 |
| User entered 'mL (mL)'                                              | Lisa Macoy (b) (4)<br>(b) (4)  | 12 Oct 2020 18:21:24 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

[If dose unit is Other, specify](#)

| Audit                                                                                                          | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System). | System              | 02 Nov 2020 21:17:43 |
| User entered 'unknown' reason for change: Data Entry Error                                                     | Etza Peters (b) (4) | 02 Nov 2020 21:17:43 |
| User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System). | System              | 02 Nov 2020 21:17:35 |
| User entered empty.                                                                                            | Lisa Macoy (b) (4)  | 12 Oct 2020 18:21:24 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

[Frequency](#)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| User entered 'once (ONCE)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 18:21:24 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

[If frequency is Other, specify](#)

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 18:21:24 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

[Route of administration](#)

| Audit                                        | User                          | Time (GMT)           |
|----------------------------------------------|-------------------------------|----------------------|
| User entered 'Intramuscular (INTRAMUSCULAR)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 18:21:24 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

If route of administration is Other, specify

| Audit               | User                          | Time (GMT)           |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 18:21:24 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date \(dd MMM yyyy\)](#)

| Audit                                                          | User                | Time (GMT)           |
|----------------------------------------------------------------|---------------------|----------------------|
| User entered '16 Oct 2020' reason for change: Data Entry Error | Etza Peters (b) (4) | 02 Nov 2020 21:17:35 |
| User entered '8 Oct 2020'                                      | Lisa Macoy (b) (4)  | 12 Oct 2020 18:21:24 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

[Start date completely unknown](#)

| Audit            | User                          | Time (GMT)           |
|------------------|-------------------------------|----------------------|
| User entered '0' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 18:21:24 |



US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

[Ongoing?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 18:21:24 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                                                          | User                | Time (GMT)           |
|----------------------------------------------------------------|---------------------|----------------------|
| User entered '16 Oct 2020' reason for change: Data Entry Error | Etza Peters (b) (4) | 02 Nov 2020 21:17:35 |
| User entered '8 Oct 2020'                                      | Lisa Macoy (b) (4)  | 12 Oct 2020 18:21:24 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

[Was this medication taken for solicited event?](#)

| Audit                 | User                          | Time (GMT)           |
|-----------------------|-------------------------------|----------------------|
| User entered 'No (N)' | Lisa Macoy (b) (4)<br>(b) (4) | 12 Oct 2020 18:21:24 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Oct 2020 18:21:24 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Oct 2020 18:21:24 |

US3532002

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:34:14**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Oct 2020 18:21:24 |

US3532002

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 09:34:14**

[Were any concomitant procedures performed?](#)

| Audit                                                      | User                | Time (GMT)           |
|------------------------------------------------------------|---------------------|----------------------|
| User entered 'Yes (Y)' reason for change: Data Entry Error | Etza Peters (b) (4) | 22 Sep 2020 21:03:27 |
| User entered 'No (N)'                                      | Etza Peters (b) (4) | 11 Aug 2020 23:27:52 |

US3532002

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '16 Sep 2020' | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 21:04:29 |



US3532002

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Procedure/Surgery](#)

| Audit                                                 | User                           | Time (GMT)           |
|-------------------------------------------------------|--------------------------------|----------------------|
| User entered 'Transforaminal lumbar interbody fusion' | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 21:04:29 |

US3532002

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:34:14**

[Indication](#)

| Audit                             | User                | Time (GMT)           |
|-----------------------------------|---------------------|----------------------|
| User entered 'Adverse Event (AE)' | Etza Peters (b) (4) | 22 Sep 2020 21:04:29 |
|                                   | (b) (4)             |                      |

US3532002

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:34:14**

[If indication is Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Etza Peters (b) (4)<br>(b) (4) | 22 Sep 2020 21:04:29 |

US3532002

**Folder: SAE USA-US077-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:34:14**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered<br>'USA-US077-2020-MRNA-1273-P301000003' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Yes (Y)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Yes (Y)' | System           | 23 Sep 2020 12:31:18 |



US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Evan'  | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Investigator's Last Name](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Reviewed for Safety.    | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Anderson' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Site Address: [Street](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Reviewed for Safety.                | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered '2015 Uppergate Drive' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Site Address: [City](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Atlanta' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Site Address: State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'GA'    | System           | 23 Sep 2020 12:31:18 |



US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Site Address: Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered '30323' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Oct 2020 15:12:24 |
| User entered 'US'    | System           | 23 Sep 2020 12:32:22 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 03 Nov 2020 13:16:14 |
| User entered '4' | System | 29 Oct 2020 19:04:14 |
| User entered '3' | System | 26 Oct 2020 15:12:34 |
| User entered '2' | System | 21 Oct 2020 21:45:59 |
| User entered '1' | System | 23 Sep 2020 12:32:22 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered<br>'USA-US077-2020-MRNA-1273-P301000003' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Yes (Y)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Yes (Y)' | System           | 23 Sep 2020 12:31:18 |



US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Evan'  | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Investigator's Last Name](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Reviewed for Safety.    | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Anderson' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Site Address: [Street](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Reviewed for Safety.                | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered '2015 Uppergate Drive' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Site Address: [City](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Atlanta' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Site Address:](#) State

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'GA'    | System           | 23 Sep 2020 12:31:18 |



US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Site Address: Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered '30323' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Oct 2020 15:12:24 |
| User entered 'US'    | System           | 23 Sep 2020 12:32:22 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 03 Nov 2020 13:16:14 |
| User entered '4' | System | 29 Oct 2020 19:04:14 |
| User entered '3' | System | 26 Oct 2020 15:12:34 |
| User entered '2' | System | 21 Oct 2020 21:45:59 |
| User entered '1' | System | 23 Sep 2020 12:32:22 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form (1)

**Generated On:** 26 Nov 2020 09:34:14

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23/Sep/2020 08:32' | System | 23 Sep 2020 12:32:22 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:34:14

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Oct 2020 15:12:24 |
| User entered '1'     | (b) (4), (b) (6) | 23 Sep 2020 12:32:22 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered<br>'USA-US077-2020-MRNA-1273-P301000003' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Yes (Y)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |



US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Yes (Y)' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Evan'  | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Investigator's Last Name](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Reviewed for Safety.    | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Anderson' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Site Address: [Street](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Reviewed for Safety.                | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered '2015 Uppergate Drive' | System           | 23 Sep 2020 12:31:18 |



US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Site Address: [City](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Atlanta' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Site Address: State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'GA'    | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Site Address: [Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered '30323' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Oct 2020 15:12:24 |
| User entered 'US'    | System           | 23 Sep 2020 12:32:22 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 03 Nov 2020 13:16:14 |
| User entered '4' | System | 29 Oct 2020 19:04:14 |
| User entered '3' | System | 26 Oct 2020 15:12:34 |
| User entered '2' | System | 21 Oct 2020 21:45:59 |
| User entered '1' | System | 23 Sep 2020 12:32:22 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form (2)

**Generated On:** 26 Nov 2020 09:34:14

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21/Oct/2020 17:45' | System | 21 Oct 2020 21:45:59 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:34:14

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Oct 2020 15:12:24 |
| User entered '1'     | (b) (4), (b) (6) | 21 Oct 2020 21:45:59 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered<br>'USA-US077-2020-MRNA-1273-P301000003' | System           | 23 Sep 2020 12:31:18 |



US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Yes (Y)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Yes (Y)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Evan'  | System           | 23 Sep 2020 12:31:18 |



US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Investigator's Last Name](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Reviewed for Safety.    | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Anderson' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Site Address: [Street](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Reviewed for Safety.                | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered '2015 Uppergate Drive' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Site Address: [City](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Atlanta' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Site Address:](#) State

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'GA'    | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Site Address: Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered '30323' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Oct 2020 15:12:24 |
| User entered 'US'    | System           | 23 Sep 2020 12:32:22 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 03 Nov 2020 13:16:14 |
| User entered '4' | System | 29 Oct 2020 19:04:14 |
| User entered '3' | System | 26 Oct 2020 15:12:34 |
| User entered '2' | System | 21 Oct 2020 21:45:59 |
| User entered '1' | System | 23 Sep 2020 12:32:22 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form (3)

**Generated On:** 26 Nov 2020 09:34:14

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26/Oct/2020 15:12' | System | 26 Oct 2020 15:12:34 |



US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:34:14

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 19:04:02 |
| User entered '1'     | (b) (4), (b) (6) | 26 Oct 2020 15:12:34 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered<br>'USA-US077-2020-MRNA-1273-P301000003' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Yes (Y)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Yes (Y)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |



US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Evan'  | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Investigator's Last Name](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Reviewed for Safety.    | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Anderson' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Site Address: [Street](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Reviewed for Safety.                | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered '2015 Uppergate Drive' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Site Address:](#) City

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Atlanta' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Site Address:](#) State

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'GA'    | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Site Address: Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered '30323' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Oct 2020 15:12:24 |
| User entered 'US'    | System           | 23 Sep 2020 12:32:22 |



US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 03 Nov 2020 13:16:14 |
| User entered '4' | System | 29 Oct 2020 19:04:14 |
| User entered '3' | System | 26 Oct 2020 15:12:34 |
| User entered '2' | System | 21 Oct 2020 21:45:59 |
| User entered '1' | System | 23 Sep 2020 12:32:22 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form (4)

**Generated On:** 26 Nov 2020 09:34:14

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '29/Oct/2020 19:04' | System | 29 Oct 2020 19:04:14 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:34:14

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Nov 2020 13:16:06 |
|                      |                  |                      |
| User entered '1'     | (b) (4), (b) (6) | 29 Oct 2020 19:04:14 |
|                      |                  |                      |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered<br>'USA-US077-2020-MRNA-1273-P301000003' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Yes (Y)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Yes (Y)' | System           | 23 Sep 2020 12:31:18 |



US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Other medically important event](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Reviewed for Safety.  | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'No (N)' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Investigator's First Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Evan'  | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Investigator's Last Name](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Reviewed for Safety.    | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Anderson' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Site Address: [Street](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Reviewed for Safety.                | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered '2015 Uppergate Drive' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

Site Address: [City](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Reviewed for Safety.   | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'Atlanta' | System           | 23 Sep 2020 12:31:18 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:34:14

[Site Address: State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered 'GA'    | System           | 23 Sep 2020 12:31:18 |



US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Site Address: Postal Code](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Sep 2020 12:32:12 |
| User entered '30323' | System           | 23 Sep 2020 12:31:18 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Oct 2020 15:12:24 |
| User entered 'US'    | System           | 23 Sep 2020 12:32:22 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:34:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 03 Nov 2020 13:16:14 |
| User entered '4' | System | 29 Oct 2020 19:04:14 |
| User entered '3' | System | 26 Oct 2020 15:12:34 |
| User entered '2' | System | 21 Oct 2020 21:45:59 |
| User entered '1' | System | 23 Sep 2020 12:32:22 |

US3532002

**Folder:** SAE USA-US077-2020-MRNA-1273-P301000003

**Form:** Safety Report Form (5)

**Generated On:** 26 Nov 2020 09:34:14

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03/Nov/2020 08:16' | System | 03 Nov 2020 13:16:14 |

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:34:14

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '1' | (b) (4), (b) (6) | 03 Nov 2020 13:16:14 |
|                  |                  |                      |
|                  |                  |                      |