

US3552140 (Prod: Saint Louis University)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:35:57

All time stamps listed in this document are displayed in GMT

US3552140

**Form: Participant Creation**

**Generated On: 26 Nov 2020 09:35:57**

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[Participant ID](#)

US3552140

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

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US3552140

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:57

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 22 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 09:35:57

|                                           |                                                                                                                                                                            |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy)                  | (b) (6) 1961                                                                                                                                                               |
| Age                                       | 59                                                                                                                                                                         |
| Age Units                                 | YEARS                                                                                                                                                                      |
| Age (Derived)                             | 59                                                                                                                                                                         |
| Sex                                       | Female <input checked="" type="radio"/><br>Male <input type="radio"/>                                                                                                      |
| Ethnicity                                 | Hispanic or Latino <input type="radio"/><br>Not Hispanic or Latino <input checked="" type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |                                                                                                                                                                            |
| White                                     | False                                                                                                                                                                      |
| Black                                     | True                                                                                                                                                                       |
| 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 09:35:57

|                                                 |                                              |
|-------------------------------------------------|----------------------------------------------|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 22 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 09:35:57

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:35:57

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:57

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | GENERALIZED RHEUMATOID<br>ARTHRITIS                              |
| Start date (dd MMM yyyy)                          | UN UNK 2015                                                      |
| 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 2015                                                         |
| Start Year (derived)                              | 2015                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:57

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | HYPERTENSION                                                     |
| 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 09:35:57

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | SJOGREN'S SYNDROME                                               |
| Start date (dd MMM yyyy)                          | UN UNK 2004                                                      |
| 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 2004                                                         |
| Start Year (derived)                              | 2004                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:57

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | FIBROMYELGIA                                                     |
| Start date (dd MMM yyyy)                          | UN UNK 2008                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |                                                                  |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2008                                                         |
| Start Year (derived)                              | 2008                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:57

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | INSOMNIA                                                         |
| Start date (dd MMM yyyy)                                | UN UNK 2015                                                      |
| 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 2015                                                         |
| Start Year (derived)                                    | 2015                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:57

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

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:35:57

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | ELECTIVE GASTRIC BYPASS SURGERY                                  |
| Start date (dd MMM yyyy)                          | UN UNK 2000                                                      |
| 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 2000                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2000                                                         |
| Start Year (derived)                              | 2000                                                             |
| Stop Month and Year (derived)                     | JAN 2000                                                         |
| Stop Year (derived)                               | 2000                                                             |

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:35:57

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

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:35:57

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | BORDERLINE ANEMIA                                                |
| Start date (dd MMM yyyy)                          | UN UNK 1979                                                      |
| 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 1979                                                         |
| Start Year (derived)                              | 1979                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:35:57

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | THROMBOPHLEBITIS                                                 |
| 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 UNK 2019                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2018                                                         |
| Start Year (derived)                              | 2018                                                             |
| Stop Month and Year (derived)                     | JAN 2019                                                         |
| Stop Year (derived)                               | 2019                                                             |

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:35:57

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | SPINAL FUSION                                                    |
| Start date (dd MMM yyyy)                          | UN JAN 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 JAN 2019                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2019                                                         |
| Start Year (derived)                              | 2019                                                             |
| Stop Month and Year (derived)                     | JAN 2019                                                         |
| Stop Year (derived)                               | 2019                                                             |

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:35:57

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | MENOPAUSE                                                        |
| Start date (dd MMM yyyy)                          | UN UNK 2013                                                      |
| 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 2013                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2013                                                         |
| Start Year (derived)                              | 2013                                                             |
| Stop Month and Year (derived)                     | JAN 2013                                                         |
| Stop Year (derived)                               | 2013                                                             |

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:35:57

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | LEFT KNEE REPLACEMENT<br>SECONDARY TO RHEUMATOID<br>ARTHRITIS    |
| 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 UNK 2018                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2018                                                         |
| Start Year (derived)                              | 2018                                                             |
| Stop Month and Year (derived)                     | JAN 2018                                                         |
| Stop Year (derived)                               | 2018                                                             |

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:35:57

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | MIXED CONNECTIVE DISEASE                                         |
| Start date (dd MMM yyyy)                          | UN SEP 2004                                                      |
| 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)                    | SEP 2004                                                         |
| Start Year (derived)                              | 2004                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:35:57

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | RAYNAUD'S DISEASE                                                |
| Start date (dd MMM yyyy)                          | UN SEP 2004                                                      |
| 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)                    | SEP 2004                                                         |
| Start Year (derived)                              | 2004                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:35:57

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | BILATERAL PITTING EDEMA                                          |
| 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 (19)

Generated On: 26 Nov 2020 09:35:57

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

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Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:35:57

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | BILATERAL CORNEAL INTACS                                         |
| Start date (dd MMM yyyy)                          | UN UNK 1994                                                      |
| 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 1994                                                         |
| Start Year (derived)                              | 1994                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:35:57

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

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Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:35:57

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | HERNIATED DISCS L3-L5                                            |
| 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 JAN 2019                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    |                                                                  |
| Start Year (derived)                              |                                                                  |
| Stop Month and Year (derived)                     | JAN 2019                                                         |
| Stop Year (derived)                               | 2019                                                             |

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

|                                           |                                      |
|-------------------------------------------|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|                                           | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 22 AUG 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 11:32 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 22 AUG 2020 11:32                    |
| Height ( <i>xxx.x</i> )                   | 66.5 in                              |
| Weight ( <i>xxx.x</i> )                   | 280 lb                               |
| BMI ( <i>xxx.x</i> )                      | 44.60922 kg/m <sup>2</sup>           |
| BMI units                                 | KG/M2                                |
| Temperature ( <i>xxx.x</i> )              | ND - Not Done                        |
| Route of measurement                      | Oral <input type="radio"/>           |
|                                           | Axillary <input type="radio"/>       |
|                                           | Other <input type="radio"/>          |
| If Other, specify                         |                                      |
| Pulse ( <i>xxx</i> )                      | ND - Not Done                        |
| Pulse units                               | BPM                                  |
| Respiratory Rate ( <i>xxx</i> )           | ND - Not Done                        |
| Respiratory Rate units                    | BREATHS/MIN                          |
| Systolic Blood Pressure ( <i>xxx</i> )    | ND - Not Done                        |
| Systolic Blood Pressure units             | MMHG                                 |
| Diastolic Blood Pressure ( <i>xxx</i> )   | ND - Not Done                        |
| Diastolic Blood Pressure units            | MMHG                                 |
| Height (derived)                          |                                      |
| Weight (derived)                          |                                      |

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:57

Date of assessment (*dd MMM yyyy*) 22 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2013

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

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**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**

OUT IN COMMUNITY,  
GROCERY SHOPPING, FAMILY  
VISITS

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

|                                                                                                                                              |                                              |
|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| <b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) | False                                        |
| <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>                                                                                                                                 | True                                         |
| <b>Specify</b>                                                                                                                               | GRANDCHILD VISITS<br>FREQUENTLY - 7 YEAR OLD |

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:57

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 22 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 09:35:57

What was the date of randomization? (dd MMM yyyy) 22 AUG 2020

What was the participant's randomization number? 144697

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 ☒

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:57

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

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 22 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 11:32 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 22 AUG 2020 11:32                                                                                      |
| Temperature (xxx.x)                 | 98.3 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 90 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 16 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 131 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 91 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 22 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 14:04 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 22 AUG 2020 14:04                                                                                      |
| Temperature (xxx.x)                 | 98.3 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 90 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 18 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 136 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 94 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

US3552140

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:57

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.*

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

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) 22 AUG 2020

What was the treatment time? (00:00-23:59) 13:34 (24 HR)

Treatment Date and Time (derived) 22 AUG 2020 13:34

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

US3552140

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:57

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

22 AUG 2020

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

12:50 (24 HR)

Collection date and time (derived)

22 AUG 2020 12:50

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:35:57

|                                        |                           |                                          |                                    |
|----------------------------------------|---------------------------|------------------------------------------|------------------------------------|
| Collection date ( <i>dd MMM yyyy</i> ) |                           |                                          | 22 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                       | 12:55                                    | 22 AUG 2020 12:55                  |
| Nasopharyngeal Swab 2                  | No                        |                                          |                                    |

US3552140

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

**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

98.3 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 22 AUG 2020 14:08

PC Open Date & Time 22 AUG 2020 13:54

PC Close Date & Time 22 AUG 2020 16:24

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

**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 97.8 °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        | 22 AUG 2020 21:18 |
| PC Open Date & Time  | 22 AUG 2020 17:19 |
| PC Close Date & Time | 23 AUG 2020 11:59 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:57

**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

97.8 °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

23 AUG 2020 21:11

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:57

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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

97.2 °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

24 AUG 2020 20:40

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:35:57

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 05:42

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:57

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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

26 AUG 2020 23:43

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:57

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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

96.6 °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

28 AUG 2020 03:35

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:57

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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

97.6 °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

29 AUG 2020 00:23

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

**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

22 AUG 2020 14:09

PC Open Date & Time

22 AUG 2020 13:54

PC Close Date & Time

22 AUG 2020 16:24

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 21:18

PC Open Date & Time

22 AUG 2020 17:19

PC Close Date & Time

23 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 21:13

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 20:40

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:57

**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

26 AUG 2020 05:42

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:57

**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

26 AUG 2020 23:44

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:57

**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

28 AUG 2020 03:35

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:57

**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

29 AUG 2020 00:24

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

**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 ☐

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 22 AUG 2020 14:09 |
| PC Open Date & Time  | 22 AUG 2020 13:54 |
| PC Close Date & Time | 22 AUG 2020 16:24 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

**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 ☐

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 22 AUG 2020 21:19 |
| PC Open Date & Time  | 22 AUG 2020 17:19 |
| PC Close Date & Time | 23 AUG 2020 11:59 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:57

**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 ☒

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:57

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 23 AUG 2020 21:13 |
| PC Open Date & Time          | 23 AUG 2020 12:00 |
| PC Close Date & Time         | 24 AUG 2020 11:59 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:57

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 ☒

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:57

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 24 AUG 2020 20:41 |
| PC Open Date & Time          | 24 AUG 2020 12:00 |
| PC Close Date & Time         | 25 AUG 2020 11:59 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:57

**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 ☒

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:57

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 26 AUG 2020 05:42 |
| PC Open Date & Time          | 25 AUG 2020 12:00 |
| PC Close Date & Time         | 26 AUG 2020 11:59 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:57

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 ☐

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:57

|                      |                   |                              |
|----------------------|-------------------|------------------------------|
|                      |                   | Yes <input type="checkbox"/> |
| PC Time stamp        | 26 AUG 2020 23:44 |                              |
| PC Open Date & Time  | 26 AUG 2020 12:00 |                              |
| PC Close Date & Time | 27 AUG 2020 11:59 |                              |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:57

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 ☒

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:57

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 28 AUG 2020 03:36 |
| PC Open Date & Time          | 27 AUG 2020 12:00 |
| PC Close Date & Time         | 28 AUG 2020 11:59 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:57

**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 ☒

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:57

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 29 AUG 2020 00:24 |
| PC Open Date & Time          | 28 AUG 2020 12:00 |
| PC Close Date & Time         | 29 AUG 2020 11:59 |

US3552140

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552140

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552140

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552140

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:57

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

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| 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)    | 21 SEP 2020                               |
| Time of assessment (00:00-23:59)    | 09:15 (24 HR)                             |
| Vital Signs Date and Time (derived) | 21 SEP 2020 09:15                         |
| Temperature (xxx.x)                 | 98.1 F                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |                                           |
| Pulse (xxx)                         | 100 beats/min                             |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 14 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 156 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 81 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

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

US3552140

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

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

STILL RECOVERING FROM  
RECENT RETINAL  
DETACHMENT SURGERY

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

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

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

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

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

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

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

US3552140

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:57

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 21 SEP 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 09:40 (24 HR)                        |
| Collection date and time (derived)     | 21 SEP 2020 09:40                    |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:35:57

| Collection date (dd MMM yyyy) |                           |                                 | 21 SEP 2020                        |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 09:45                           | 21 SEP 2020 09:45                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552140

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552140

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552140

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:57

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

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

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

US3552140

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:57

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.*

US3552140

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:57

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 16 OCT 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 14:20 (24 HR)                        |
| Collection date and time (derived)     | 16 OCT 2020 14:20                    |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**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

29 OCT 2020 07:16:12

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| TIMEPOINT                                                                                                                                                                       | DAY 78                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                  |
| Date and time of submission                                                                                                                                                     | 05 NOV 2020 06:31:08                                             |
| Patient Cloud Open Date & Time                                                                                                                                                  | 05 NOV 2020 00:01                                                |
| Patient Cloud Close Date & Time                                                                                                                                                 | 09 NOV 2020 23:59                                                |

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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 <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                  |
| Date and time of submission                                                                                                                                                     | 19 NOV 2020 07:16:39                                             |
| Patient Cloud Open Date & Time                                                                                                                                                  | 19 NOV 2020 00:01                                                |
| Patient Cloud Close Date & Time                                                                                                                                                 | 23 NOV 2020 23:59                                                |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2020 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2020 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2020 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2020 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

20 NOV 2020 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2020 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

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

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2020 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2020 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

18 DEC 2020 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

25 DEC 2020 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| TIMEPOINT                                                                                                                                                                       | DAY 131                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JAN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

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

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JAN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JAN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| TIMEPOINT                                                                                                                                                                       | DAY 159                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JAN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**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 ☐

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

05 FEB 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

12 FEB 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

19 FEB 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

26 FEB 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

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

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 APR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 APR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 APR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| TIMEPOINT                                                                                                                                                                       | DAY 313                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 AUG 2021 00:01

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06 AUG 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**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°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 ☐

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

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09 AUG 2021 00:01

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13 AUG 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**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 ☐

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**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 ☐ 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 ☐

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**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°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 ☐

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

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

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

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

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

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

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

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

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| TIMEPOINT                                                                                                                                                                       | DAY 516                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

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21 JAN 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**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 ☐

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

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28 JAN 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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04 FEB 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

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 ☐

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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11 FEB 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

**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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18 FEB 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

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

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

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25 FEB 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| TIMEPOINT                                                                                                                                                                       | DAY 558                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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04 MAR 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**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 ☐

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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11 MAR 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**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 ☐

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

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14 MAR 2022 00:01

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18 MAR 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**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 ☐

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

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25 MAR 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

DAY 586

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3552140**

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

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Date and time of submission

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28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**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 ☐

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

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

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| TIMEPOINT                                                                                                                                                                       | DAY 635                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

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**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| TIMEPOINT                                                                                                                                                                       | DAY 649                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| TIMEPOINT                                                                                                                                                                       | DAY 656                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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10 JUN 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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17 JUN 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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20 JUN 2022 00:01

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24 JUN 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**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 ☐

**US3552140**

**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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27 JUN 2022 00:01

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01 JUL 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

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

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

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04 JUL 2022 00:01

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08 JUL 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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11 JUL 2022 00:01

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15 JUL 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

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

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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22 JUL 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

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

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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25 JUL 2022 00:01

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29 JUL 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**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 ☐ 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 ☐

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

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

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

| 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"/>                                               |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

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 ☐ 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 ☐

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2022 23:59

US3552140

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3552140

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552140

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:35:57

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

US3552140

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:35:57

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3552140

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:35:57

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US089-2020-MRNA-1273-P30<br>1000002                                                                                                                          |
| Adverse event                                                  | RETINAL DETACHMENT OF<br>LEFT EYE                                                                                                                                |
| 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)                                       | 08 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)                         | 12 SEP 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input checked="" type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | False                                                                                                                                                            |
| Hospital Admission Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Hospital Discharge Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>                                                                           |
| Number of Days in ICU                                          |                                                                                                                                                                  |

v6.020 DTW (1102)

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US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Persistent or significant disability or incapacity                           | False                                                                                                                                                                                                                                                                           |
| Congenital anomaly or birth defect                                           | False                                                                                                                                                                                                                                                                           |
| Other medically important event                                              | True                                                                                                                                                                                                                                                                            |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Relationship to Study Procedure                                              | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Action taken with investigational product                                    | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product <input checked="" type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                         |
| Other action taken (check all that apply)                                    |                                                                                                                                                                                                                                                                                 |
| None                                                                         | False                                                                                                                                                                                                                                                                           |
| Concomitant Medication                                                       | True                                                                                                                                                                                                                                                                            |
| Concomitant Procedure                                                        | 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                                                                    |                                                                                                                                                                                                                                                                                 |

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

CONTACTED SUBJECT VIA  
PHONE AT 9:49 ON 9/10/2020 TO  
FOLLOW UP ON NEW  
MEDICATION; SUBJECT  
SHARED THAT SHE WAS  
CURRENTLY EXPERIENCING  
NEW VISION  
CHANGES/PARTIAL VISION  
LOSS IN HER LEFT EYE. SHE  
HAD ALREADY CONTACTED  
HER OPHTHALMOLOGIST AND  
WAS WAITING FOR A RETURN  
CALL. SEEN BY  
OPHTHALMOLOGIST 9/10,  
DIAGNOSED WITH RETINAL  
DETACHMENT OF LEFT EYE,  
SURGICALLY CORRECTED ON  
9/11. THREE NEW  
MEDICATIONS STARTED, WILL  
UPDATE CON MEDS WHEN  
NAMES ARE AVAILABLE.  
RECORDS NOT YET AVAILABLE  
TO SITE, WILL SEND WHEN WE  
HAVE RECEIVED THEM.

WILL FAX THIS AFTERNOON,  
NO LAB TESTS PERFORMED.  
SUBJECT HAS HISTORY OF  
AUTOIMMUNE DISEASE,  
UNKNOWN IF THERE IS FAMILY  
HISTORY. NO SUSPECTED  
CAUSE LISTED IN MEDICAL  
RECORDS.

|                                                            |   |
|------------------------------------------------------------|---|
| 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)       |   |

US3552140

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US089-2020-MRNA-1273-P30<br>1000007                                                                                                                          |
| Adverse event                                                  | HORSESHOE TEAR OF RIGHT<br>EYE                                                                                                                                   |
| 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)                                       | 01 OCT 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 06 OCT 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input checked="" type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | False                                                                                                                                                            |
| Hospital Admission Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Hospital Discharge Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>                                                                           |
| Number of Days in ICU                                          |                                                                                                                                                                  |

v6.020 DTW (1102)

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US3552140

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Persistent or significant disability or incapacity                           | False                                                                                                                                                                                                                                                                           |
| Congenital anomaly or birth defect                                           | False                                                                                                                                                                                                                                                                           |
| Other medically important event                                              | True                                                                                                                                                                                                                                                                            |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Relationship to Study Procedure                                              | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Action taken with investigational product                                    | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>                                                                         |
| Other action taken (check all that apply)                                    |                                                                                                                                                                                                                                                                                 |
| None                                                                         | 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                                                                    |                                                                                                                                                                                                                                                                                 |

US3552140

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

---

SUBJECT REPORTED  
RECEIVING LASER EYE  
TREATMENT TO FIX A  
HORSESHOE TEAR OF RIGHT  
EYE. STATES SHE WAS AT HER  
EYE DOCTOR FOR AN  
APPOINTMENT ABOUT HER  
DRY EYES AND UPON EXAM  
THEY FOUND THE TEAR AND  
WANTED TO FIX IT. NO  
COMPLICATIONS  
POST-PROCEDURE. HAS TAKEN  
IBUPROFEN X2 SINCE  
PROCEDURE FOR EYE PAIN  
WHICH HAS SINCE RESOLVED.

---

|                                                            |   |
|------------------------------------------------------------|---|
| 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) |  |
|------------------------------------------------------|--|

---

US3552140

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

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

**Generated On: 26 Nov 2020 09:35:57**

---

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

Yes ☒

No ☐

---

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

---

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:57

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

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:57

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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 2015                         |
| 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 (2)

Generated On: 26 Nov 2020 09:35:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:57

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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 2012                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | PILOCARPINE                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                    | Yes <input type="checkbox"/><br>No <input checked="" type="checkbox"/>                                                                                                                                                                                                                                                                                                                                                                                    |
| Indication                     | SJOGREN'S SYNDROME                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose per administration        | 5                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 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 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 checked="" 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 (3)

Generated On: 26 Nov 2020 09:35:57

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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 2004                         |
| 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 (4)

Generated On: 26 Nov 2020 09:35:57

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | SAVELLA                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | FIBROMYALGIA                                                                                                                                                                                                                                                                                                                                                                                                             |
| 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 type="radio"/><br>twice daily <input checked="" type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:57

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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 2008                         |
| 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 (5)

Generated On: 26 Nov 2020 09:35:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:57

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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 2015                         |
| 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 (6)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | CYCLOBENZAPRINE                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Prophylaxis                    | Yes <input type="checkbox"/><br>No <input checked="" type="checkbox"/>                                                                                                                                                                                                                                                                                                                                                                                    |
| Indication                     | MUSCLE PAIN DUE TO FIBROMYALGIA                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Dose per administration        | 10                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 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 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 checked="" 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"/>                                                                                                                                                                                                                                                     |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Intramuscular            | <input type="checkbox"/>         |
|                                                    | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                    | Intralesional            | <input type="checkbox"/>         |
|                                                    | Intraperitoneal          | <input type="checkbox"/>         |
|                                                    | Nasal                    | <input type="checkbox"/>         |
|                                                    | Vaginal                  | <input type="checkbox"/>         |
|                                                    | Rectal                   | <input type="checkbox"/>         |
|                                                    | Intravenous              | <input type="checkbox"/>         |
|                                                    | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                    | Intravenous Drip         | <input type="checkbox"/>         |
|                                                    | Other                    | <input type="checkbox"/>         |
| <hr/>                                              |                          |                                  |
| If route of administration is Other, specify <hr/> |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | UN UNK 2010                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?                                           | Yes                      | <input checked="" type="radio"/> |
|                                                    | No                       | <input type="radio"/>            |
| <hr/>                                              |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <hr/>       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| <hr/>                                              |                          |                                  |
| Separate Dosage Number (derived)                   |                          | <hr/>                            |
| Interval Dosage Unit Number (derived)              |                          | <hr/>                            |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|                                                    | 803                      | <input type="radio"/>            |
|                                                    | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:35:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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|                                                                   |                                      |                                     |
|-------------------------------------------------------------------|--------------------------------------|-------------------------------------|
|                                                                   | Respiratory (Inhalation)             | <input type="checkbox"/>            |
|                                                                   | Intralesional                        | <input type="checkbox"/>            |
|                                                                   | Intraperitoneal                      | <input type="checkbox"/>            |
|                                                                   | Nasal                                | <input type="checkbox"/>            |
|                                                                   | Vaginal                              | <input type="checkbox"/>            |
|                                                                   | Rectal                               | <input type="checkbox"/>            |
|                                                                   | Intravenous                          | <input type="checkbox"/>            |
|                                                                   | Intravenous Bolus                    | <input type="checkbox"/>            |
|                                                                   | Intravenous Drip                     | <input type="checkbox"/>            |
|                                                                   | Other                                | <input type="checkbox"/>            |
| <hr/>                                                             |                                      |                                     |
| If route of administration is Other, specify <input type="text"/> |                                      |                                     |
| <hr/>                                                             |                                      |                                     |
| Start date (dd MMM yyyy)                                          | UN UNK 2000                          |                                     |
| Start date completely unknown                                     | False                                |                                     |
| Ongoing?                                                          | Yes <input checked="" type="radio"/> | No <input type="radio"/>            |
| <hr/>                                                             |                                      |                                     |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                                      |                                     |
| <hr/>                                                             |                                      |                                     |
| Was this medication taken for solicited event?                    | Yes <input type="radio"/>            | No <input checked="" type="radio"/> |
| <hr/>                                                             |                                      |                                     |
| Separate Dosage Number (derived)                                  | <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 (8)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:35:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:35:57

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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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 2013                         |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | WELLBUTRIN ER                                                                                                                                                                                                                                                                                                                                                                                                            |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | ANXIETY                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Dose per administration              | 150                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 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 (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)                                          |                          | 09 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)                                  |                          | 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 (11)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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|                                                                   |                          |                                     |
|-------------------------------------------------------------------|--------------------------|-------------------------------------|
|                                                                   | Respiratory (Inhalation) | <input type="checkbox"/>            |
|                                                                   | Intralesional            | <input type="checkbox"/>            |
|                                                                   | Intraperitoneal          | <input type="checkbox"/>            |
|                                                                   | Nasal                    | <input type="checkbox"/>            |
|                                                                   | Vaginal                  | <input type="checkbox"/>            |
|                                                                   | Rectal                   | <input type="checkbox"/>            |
|                                                                   | Intravenous              | <input type="checkbox"/>            |
|                                                                   | Intravenous Bolus        | <input type="checkbox"/>            |
|                                                                   | Intravenous Drip         | <input type="checkbox"/>            |
|                                                                   | Other                    | <input type="checkbox"/>            |
| <hr/>                                                             |                          |                                     |
| If route of administration is Other, specify <input type="text"/> |                          |                                     |
| <hr/>                                                             |                          |                                     |
| Start date (dd MMM yyyy)                                          |                          | 11 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)                            |                          | 18 SEP 2020                         |
| Was this medication taken for solicited event?                    | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| Separate Dosage Number (derived)                                  |                          | 4                                   |
| Interval Dosage Unit Number (derived)                             |                          | 1                                   |
| Interval Dosage Definition (derived)                              | 802                      | <input type="checkbox"/>            |
|                                                                   | 803                      | <input type="checkbox"/>            |
|                                                                   | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

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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)                                          |                          | 11 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)                                  |                          | 3                                |
| Interval Dosage Unit Number (derived)                             |                          | 1                                |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

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

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Form: Prior/Concomitant Medication and Vaccination (13)

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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)                                          |                          | 12 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)                                  |                          | 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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Form: Prior/Concomitant Medication and Vaccination (14)

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

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Form: Prior/Concomitant Medication and Vaccination (14)

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

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:35:57

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | IBUPROFEN                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | EYE PAIN RELATED TO EYE<br>PROCEDURE                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose per administration        | 600                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input 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"/>                                                                                                                                                                                                                                   |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:35:57

|                                                    |                                     |                       |
|----------------------------------------------------|-------------------------------------|-----------------------|
|                                                    | Intramuscular                       | <input type="radio"/> |
|                                                    | Respiratory (Inhalation)            | <input type="radio"/> |
|                                                    | Intralesional                       | <input type="radio"/> |
|                                                    | Intraperitoneal                     | <input type="radio"/> |
|                                                    | Nasal                               | <input type="radio"/> |
|                                                    | Vaginal                             | <input type="radio"/> |
|                                                    | Rectal                              | <input type="radio"/> |
|                                                    | Intravenous                         | <input type="radio"/> |
|                                                    | Intravenous Bolus                   | <input type="radio"/> |
|                                                    | Intravenous Drip                    | <input type="radio"/> |
|                                                    | Other                               | <input type="radio"/> |
| <hr/>                                              |                                     |                       |
| If route of administration is Other, specify _____ |                                     |                       |
| Start date (dd MMM yyyy)                           | 01 OCT 2020                         |                       |
| Start date completely unknown                      | False                               |                       |
| Ongoing?                                           | Yes <input type="radio"/>           |                       |
|                                                    | No <input checked="" type="radio"/> |                       |
| <hr/>                                              |                                     |                       |
| If not Ongoing, End date (dd MMM yyyy)             |                                     | 02 OCT 2020           |
| Was this medication taken for solicited event?     | Yes <input type="radio"/>           |                       |
|                                                    | No <input checked="" type="radio"/> |                       |
| <hr/>                                              |                                     |                       |
| Separate Dosage Number (derived)                   | _____                               |                       |
| Interval Dosage Unit Number (derived)              | _____                               |                       |
| Interval Dosage Definition (derived)               | 802 <input type="radio"/>           |                       |
|                                                    | 803 <input type="radio"/>           |                       |
|                                                    | 804 <input type="radio"/>           |                       |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:35:57

Name of Medication CYCLOPENTOLATE 2%

Prophylaxis Yes ☐  
No ☒

Indication CRYOTHERAPY OF RIGHT EYE

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify DROP IN RIGHT EYE

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐  
Intramuscular ☐

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:35:57

|                                                |                          |                                  |
|------------------------------------------------|--------------------------|----------------------------------|
|                                                | Respiratory (Inhalation) | <input type="radio"/>            |
|                                                | Intralesional            | <input type="radio"/>            |
|                                                | Intraperitoneal          | <input type="radio"/>            |
|                                                | Nasal                    | <input type="radio"/>            |
|                                                | Vaginal                  | <input type="radio"/>            |
|                                                | Rectal                   | <input type="radio"/>            |
|                                                | Intravenous              | <input type="radio"/>            |
|                                                | Intravenous Bolus        | <input type="radio"/>            |
|                                                | Intravenous Drip         | <input type="radio"/>            |
|                                                | Other                    | <input checked="" type="radio"/> |
| If route of administration is Other, specify   | OPHTHALMIC SOLUTION      |                                  |
| Start date (dd MMM yyyy)                       | 06 OCT 2020              |                                  |
| Start date completely unknown                  | False                    |                                  |
| Ongoing?                                       | Yes                      | <input type="radio"/>            |
|                                                | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)         | 06 OCT 2020              |                                  |
| Was this medication taken for solicited event? | Yes                      | <input type="radio"/>            |
|                                                | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)               |                          |                                  |
| Interval Dosage Unit Number (derived)          |                          |                                  |
| Interval Dosage Definition (derived)           | 802                      | <input type="radio"/>            |
|                                                | 803                      | <input type="radio"/>            |
|                                                | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:35:57

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | PHENYLEPHRINE 2.5%                                                                                                                                                                                                                                                                                                                                                                                                       |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | CRYOTHERAPY OF RIGHT EYE                                                                                                                                                                                                                                                                                                                                                                                                 |
| Dose per administration        | 1                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input checked="" type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify | DROP IN RIGHT EYE                                                                                                                                                                                                                                                                                                                                                                                                        |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                                       |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:35:57

|                                                |                          |                                  |
|------------------------------------------------|--------------------------|----------------------------------|
|                                                | Respiratory (Inhalation) | <input type="radio"/>            |
|                                                | Intralesional            | <input type="radio"/>            |
|                                                | Intraperitoneal          | <input type="radio"/>            |
|                                                | Nasal                    | <input type="radio"/>            |
|                                                | Vaginal                  | <input type="radio"/>            |
|                                                | Rectal                   | <input type="radio"/>            |
|                                                | Intravenous              | <input type="radio"/>            |
|                                                | Intravenous Bolus        | <input type="radio"/>            |
|                                                | Intravenous Drip         | <input type="radio"/>            |
|                                                | Other                    | <input checked="" type="radio"/> |
| If route of administration is Other, specify   | OPHTHALMIC SOLUTION      |                                  |
| Start date (dd MMM yyyy)                       | 06 OCT 2020              |                                  |
| Start date completely unknown                  | False                    |                                  |
| Ongoing?                                       | Yes                      | <input type="radio"/>            |
|                                                | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)         | 06 OCT 2020              |                                  |
| Was this medication taken for solicited event? | Yes                      | <input type="radio"/>            |
|                                                | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)               |                          |                                  |
| Interval Dosage Unit Number (derived)          |                          |                                  |
| Interval Dosage Definition (derived)           | 802                      | <input type="radio"/>            |
|                                                | 803                      | <input type="radio"/>            |
|                                                | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:35:57

|                    |                                                                  |
|--------------------|------------------------------------------------------------------|
| Name of Medication | TROPICAMIDE 1%                                                   |
| Prophylaxis        | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |

|            |                          |
|------------|--------------------------|
| Indication | CRYOTHERAPY OF RIGHT EYE |
|------------|--------------------------|

|                         |   |
|-------------------------|---|
| Dose per administration | 1 |
|-------------------------|---|

|           |                                                                                                                                                                                                                                                                                  |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Dose unit | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input checked="" type="radio"/> |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                |                   |
|--------------------------------|-------------------|
| If dose unit is Other, specify | DROP IN RIGHT EYE |
|--------------------------------|-------------------|

|           |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Frequency | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                |  |
|--------------------------------|--|
| If frequency is Other, specify |  |
|--------------------------------|--|

|                         |                                                                                                                                                                                                                    |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Route of administration | Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/> |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:35:57

|                                                |                          |                                  |
|------------------------------------------------|--------------------------|----------------------------------|
|                                                | Respiratory (Inhalation) | <input type="radio"/>            |
|                                                | Intralesional            | <input type="radio"/>            |
|                                                | Intraperitoneal          | <input type="radio"/>            |
|                                                | Nasal                    | <input type="radio"/>            |
|                                                | Vaginal                  | <input type="radio"/>            |
|                                                | Rectal                   | <input type="radio"/>            |
|                                                | Intravenous              | <input type="radio"/>            |
|                                                | Intravenous Bolus        | <input type="radio"/>            |
|                                                | Intravenous Drip         | <input type="radio"/>            |
|                                                | Other                    | <input checked="" type="radio"/> |
| If route of administration is Other, specify   | OPHTHALMIC SOLUTION      |                                  |
| Start date (dd MMM yyyy)                       | 06 OCT 2020              |                                  |
| Start date completely unknown                  | False                    |                                  |
| Ongoing?                                       | Yes                      | <input type="radio"/>            |
|                                                | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)         | 06 OCT 2020              |                                  |
| Was this medication taken for solicited event? | Yes                      | <input type="radio"/>            |
|                                                | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)               |                          |                                  |
| Interval Dosage Unit Number (derived)          |                          |                                  |
| Interval Dosage Definition (derived)           | 802                      | <input type="radio"/>            |
|                                                | 803                      | <input type="radio"/>            |
|                                                | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:35:57

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | INFLUENZA VACCINE                                                                                                                                                                                                                                                                                                                                                                                                        |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | INFLUENZA PROPHYLAXIS                                                                                                                                                                                                                                                                                                                                                                                                    |
| Dose per administration        | 1                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input checked="" type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify | INJECTION                                                                                                                                                                                                                                                                                                                                                                                                                |
| 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 (19)

Generated On: 26 Nov 2020 09:35:57

|                                                                   |                          |                                     |
|-------------------------------------------------------------------|--------------------------|-------------------------------------|
|                                                                   | 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 NOV 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)                            |                          | 17 NOV 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"/>        |

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**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 09:35:57**

---

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 09:35:57

| Procedure/Surgery date (dd MMM<br>yyyy) | Procedure/Surgery                                                   | Indication    | If indication is Other, specify |
|-----------------------------------------|---------------------------------------------------------------------|---------------|---------------------------------|
| 11 SEP 2020                             | LEFT EYE VITRECTOMY<br>MEMBRANECTOMY [RETINAL<br>DETACHMENT REPAIR] | Adverse Event |                                 |
| 01 OCT 2020                             | LASER PHOTOCOAGULATION<br>REPAIR OF RIGHT RETINAL<br>HORSESHOE TEAR | Adverse Event |                                 |
| 06 OCT 2020                             | CRYOTHERAPY OF RIGHT EYE                                            | Adverse Event |                                 |

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:35:57

Date of dosing discontinuation (dd MMM yyyy)

21 SEP 2020

Primary reason for dosing discontinuation

AE (specify) ☒

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

AE #2

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:35:57

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 ☐

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

|                                                                |                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                          | USA-US089-2020-MRNA-1273-P301000002                              |
| 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 type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                      | SHARON                                                           |
| Investigator's Last Name                                       | FREY                                                             |
| Site Address: Street                                           |                                                                  |
| Site Address: City                                             |                                                                  |
| Site Address: State                                            | MO                                                               |
| Site Address: Postal Code                                      |                                                                  |
| Investigator Country                                           | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                             | 5                                                                |

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Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:35:57

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US089-2020-MRNA-1273-P301000002                              |
| 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 type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | SHARON                                                           |
| Investigator's Last Name                                                                                                                                                                      | FREY                                                             |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           | MO                                                               |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 11/SEP/2020 09:55                                                |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True                                                             |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:35:57

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US089-2020-MRNA-1273-P301000002                              |
| 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 type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | SHARON                                                           |
| Investigator's Last Name                                                                                                                                                                      | FREY                                                             |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           | MO                                                               |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 13/SEP/2020 07:26                                                |
| 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                                                             |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:35:57

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US089-2020-MRNA-1273-P301000002                              |
| 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 type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | SHARON                                                           |
| Investigator's Last Name                                                                                                                                                                      | FREY                                                             |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           | MO                                                               |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 18/SEP/2020 11:42                                                |
| 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                                                             |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:35:57

|                                                                                                                                                                                               |                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US089-2020-MRNA-1273-P301000002                           |
| 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 type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | SHARON                                                        |
| Investigator's Last Name                                                                                                                                                                      | FREY                                                          |
| Site Address: Street                                                                                                                                                                          |                                                               |
| Site Address: City                                                                                                                                                                            |                                                               |
| Site Address: State                                                                                                                                                                           | MO                                                            |
| Site Address: Postal Code                                                                                                                                                                     |                                                               |
| Investigator Country                                                                                                                                                                          | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                             |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 30/OCT/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                                                          |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:35:57

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US089-2020-MRNA-1273-P301000002                              |
| 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 type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | SHARON                                                           |
| Investigator's Last Name                                                                                                                                                                      | FREY                                                             |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           | MO                                                               |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 10/NOV/2020 09:54                                                |
| 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                                                             |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

|                                                                |                                                               |
|----------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                          | USA-US089-2020-MRNA-1273-P301000007                           |
| Serious                                                        | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death                                                          | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening                                               | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity             | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                             | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event                                | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name                                      | SHARON                                                        |
| Investigator's Last Name                                       | FREY                                                          |
| Site Address: Street                                           |                                                               |
| Site Address: City                                             |                                                               |
| Site Address: State                                            | MO                                                            |
| Site Address: Postal Code                                      |                                                               |
| Investigator Country                                           | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                             | 5                                                             |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:35:57

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US089-2020-MRNA-1273-P301000007                              |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | SHARON                                                           |
| Investigator's Last Name                                                                                                                                                                      | FREY                                                             |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           | MO                                                               |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 05/OCT/2020 13:26                                                |
| 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                                                             |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:35:57

|                                                                                                                                                                                               |                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US089-2020-MRNA-1273-P301000007                           |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | SHARON                                                        |
| Investigator's Last Name                                                                                                                                                                      | FREY                                                          |
| Site Address: Street                                                                                                                                                                          |                                                               |
| Site Address: City                                                                                                                                                                            |                                                               |
| Site Address: State                                                                                                                                                                           | MO                                                            |
| Site Address: Postal Code                                                                                                                                                                     |                                                               |
| Investigator Country                                                                                                                                                                          | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                             |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 13/OCT/2020 16:45                                             |
| 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                                                          |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:35:57

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US089-2020-MRNA-1273-P301000007                              |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | SHARON                                                           |
| Investigator's Last Name                                                                                                                                                                      | FREY                                                             |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           | MO                                                               |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 29/OCT/2020 08:26                                                |
| 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                                                             |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:35:57

|                                                                                                                                                                                               |                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US089-2020-MRNA-1273-P301000007                           |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | SHARON                                                        |
| Investigator's Last Name                                                                                                                                                                      | FREY                                                          |
| Site Address: Street                                                                                                                                                                          |                                                               |
| Site Address: City                                                                                                                                                                            |                                                               |
| Site Address: State                                                                                                                                                                           | MO                                                            |
| Site Address: Postal Code                                                                                                                                                                     |                                                               |
| Investigator Country                                                                                                                                                                          | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                             |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 10/NOV/2020 09:54                                             |
| 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                                                          |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:35:57

|                                                                                                                                                                                               |                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US089-2020-MRNA-1273-P301000007                           |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | SHARON                                                        |
| Investigator's Last Name                                                                                                                                                                      | FREY                                                          |
| Site Address: Street                                                                                                                                                                          |                                                               |
| Site Address: City                                                                                                                                                                            |                                                               |
| Site Address: State                                                                                                                                                                           | MO                                                            |
| Site Address: Postal Code                                                                                                                                                                     |                                                               |
| Investigator Country                                                                                                                                                                          | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 5                                                             |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 24/NOV/2020 13:19                                             |
| 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

US3552140 (Prod: Saint Louis University)

US3552140

**Form: Participant Creation**

**Generated On: 26 Nov 2020 09:35:57**

[Participant ID](#)

| Audit                    | User                                           | Time (GMT)           |
|--------------------------|------------------------------------------------|----------------------|
| User entered 'US3552140' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 22 Aug 2020 18:04:09 |

US3552140

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:57

[Was this visit performed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:05:12 |

US3552140

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:57

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

| Audit                      | User                                            | Time (GMT)           |
|----------------------------|-------------------------------------------------|----------------------|
| User entered '22 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 22 Aug 2020 18:04:11 |

US3552140

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:05:12 |

**US3552140**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:35:57**

[Folder OID](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 24 Aug 2020 12:05:12 |

US3552140

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:57

Date of Birth (MMM yyyy)

| Audit                      | User                                           | Time (GMT)           |
|----------------------------|------------------------------------------------|----------------------|
| User entered (b) (6) 1961' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 22 Aug 2020 18:04:12 |

US3552140

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:57

[Age](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '59' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:05:36 |

US3552140

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:35:57**

[Age Units](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 24 Aug 2020 12:05:36 |

US3552140

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:57

[Age \(Derived\)](#)

| Audit             | User   | Time (GMT)           |
|-------------------|--------|----------------------|
| User entered '59' | System | 22 Aug 2020 18:05:03 |

US3552140

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:57

[Sex](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User entered 'Female (F)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:05:36 |

US3552140

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:57

[Ethnicity](#)

| Audit                                                          | User                              | Time (GMT)           |
|----------------------------------------------------------------|-----------------------------------|----------------------|
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:05:36 |

US3552140

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:57

[White](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:05:36 |

US3552140

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:57

[Black](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:05:36 |

US3552140

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:57

[Asian](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:05:36 |

US3552140

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:35:57**

[American Indian or Alaska Native](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:05:36 |

US3552140

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:35:57**

[Native Hawaiian or other Pacific Islander](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:05:36 |

US3552140

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:57

[Other](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:05:36 |

US3552140

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:35:57**

[If race is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:05:36 |

US3552140

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:57

Unknown

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:05:36 |

US3552140

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:57

[Not reported](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:05:36 |

US3552140

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '22 Aug 2020' | (b) (4), (b) (6) | 22 Aug 2020 18:05:03 |
|                            |                  |                      |

US3552140

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Aug 2020' | System | 22 Aug 2020 18:05:03 |

US3552140

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 22 Aug 2020 18:05:03 |

US3552140

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:57

[Protocol Version](#)

| Audit                          | User             | Time (GMT)           |
|--------------------------------|------------------|----------------------|
| User entered 'Amendment 2 (2)' | (b) (4), (b) (6) | 22 Aug 2020 18:05:03 |
|                                |                  |                      |

US3552140

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:57

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Aug 2020 18:05:03 |
|                        |                  |                      |

US3552140

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:57

If No, indicate reason for screen fail

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 22 Aug 2020 18:05:03 |
|                     |                  |                      |

US3552140

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:57

If reason for screen fail is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 22 Aug 2020 18:05:03 |
|                     |                  |                      |

US3552140

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:35:57**

[Was this participant screened previously?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Aug 2020 18:05:03 |
|                       |                  |                      |

US3552140

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:35:57**

[If Yes, previous participant number](#)

| Audit               | User                                           | Time (GMT)           |
|---------------------|------------------------------------------------|----------------------|
| User entered empty. | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 22 Aug 2020 18:04:11 |

US3552140

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:35:57**

[Enrollment Trigger](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Aug 2020 18:05:11 |

US3552140

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:35:57

Did the participant meet all eligibility criteria?

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Aug 2020 18:05:11 |
|                        |                  |                      |

US3552140

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 09:35:57**

[Were any significant conditions reported?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:07:59 |

US3552140

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:57

[Condition](#)

| Audit                                                                                                                                                                                                                                                                           | User                      | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| User closed query 'Per DM CLR: Please specify the location of RHEUMATOID ARTHRITIS. 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)          | 05 Oct 2020 10:50:46 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\23.0.                                                                 | Coder Import (b) (4)      | 01 Oct 2020 19:39:51 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                     | (b) (4)                   | 01 Oct 2020 19:39:51 |
| Data point term sent to Coder                                                                                                                                                                                                                                                   | System                    | 01 Oct 2020 19:39:24 |
| Query 'Per DM CLR: Please specify the location of RHEUMATOID ARTHRITIS. 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). | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:38:53 |
| Coding entries removed.                                                                                                                                                                                                                                                         | (b) (4)                   |                      |
|                                                                                                                                                                                                                                                                                 | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:38:42 |
| User entered 'generalized RHEUMATOID ARTHRITIS' reason for change: Per Query Resolution                                                                                                                                                                                         | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:38:42 |
| User opened query 'Per DM CLR: Please specify the location of RHEUMATOID ARTHRITIS. 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)          | 25 Sep 2020 12:28:17 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\23.0.                                                                 | Coder Import (b) (4)      | 24 Aug 2020 12:10:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                     | (b) (4)                   | 24 Aug 2020 12:10:39 |
| Data point term sent to Coder                                                                                                                                                                                                                                                   | System                    | 24 Aug 2020 12:09:22 |
| User entered 'rheumatoid arthritis'                                                                                                                                                                                                                                             | Stanley Doublin (b) (4)   | 24 Aug 2020 12:08:40 |
|                                                                                                                                                                                                                                                                                 | (b) (4)                   |                      |

US3552140

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2015' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:08:40 |

US3552140

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:08:40 |

US3552140

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:08:40 |

US3552140

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:08:40 |

US3552140

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:08:40 |

US3552140

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2015' | System | 24 Aug 2020 12:08:40 |

US3552140

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2015' | System | 24 Aug 2020 12:08:40 |

US3552140

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:08:40 |

US3552140

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:08:40 |

US3552140

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:57

[Condition](#)

| Audit                                                                                                                                                                                         | User                    | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User coded data point as SOC: Vascular disorders, HLG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4)    | 24 Aug 2020 12:10:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                  | Coder Import (b) (4)    | 24 Aug 2020 12:10:40 |
| Data point term sent to Coder                                                                                                                                                                 | System                  | 24 Aug 2020 12:09:23 |
| User entered 'hypertension'                                                                                                                                                                   | Stanley Doublin (b) (4) | 24 Aug 2020 12:08:54 |

US3552140

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2012' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:08:54 |

US3552140

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:08:54 |

US3552140

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:08:54 |

US3552140

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:08:54 |

US3552140

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:08:54 |

US3552140

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2012' | System | 24 Aug 2020 12:08:54 |

US3552140

**Folder:** Screening

**Form:** Medical History (2)

**Generated On:** 26 Nov 2020 09:35:57

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2012' | System | 24 Aug 2020 12:08:54 |

US3552140

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:08:54 |

US3552140

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:08:54 |

US3552140

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:57

[Condition](#)

| Audit                                                                                                                                                                                                                                             | User                   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Connective tissue disorders (excl congenital), HLT: Connective tissue disorders NEC, PT: Sjogren's syndrome, LLT: Sjogren's syndrome - version MedDRA\\23.0. | Coder Import (b) (4)   | 24 Aug 2020 12:11:29 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                                      | Coder Import (b) (4)   | 24 Aug 2020 12:11:29 |
| Data point term sent to Coder                                                                                                                                                                                                                     | System                 | 24 Aug 2020 12:10:25 |
| User entered 'sjogren's syndrome'                                                                                                                                                                                                                 | Stanley Dublin (b) (4) | 24 Aug 2020 12:09:30 |

US3552140

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2004' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:09:30 |

US3552140

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:09:30 |

US3552140

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:57

[Condition ongoing at study entry](#)

| Audit                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                 | 24 Aug 2020 12:09:38 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 24 Aug 2020 12:09:38 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | Stanley Dublin (b) (4) | 24 Aug 2020 12:09:38 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 24 Aug 2020 12:09:30 |
| User entered empty.                                                                    | Stanley Dublin (b) (4) | 24 Aug 2020 12:09:30 |

US3552140

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:09:30 |

US3552140

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:09:30 |

US3552140

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2004' | System | 24 Aug 2020 12:09:30 |

US3552140

**Folder:** Screening

**Form:** Medical History (3)

**Generated On:** 26 Nov 2020 09:35:57

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2004' | System | 24 Aug 2020 12:09:30 |

US3552140

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:09:30 |

US3552140

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:09:30 |

US3552140

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:35:57

[Condition](#)

| Audit                                                                                                                                                                                | User                               | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Fibromyalgia, LLT: Fibromyalgia - version MedDRA\23.0. | Coder Import (b) (4)<br>(b) (4)    | 24 Aug 2020 20:20:36 |
| 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 Aug 2020 20:20:36 |
| Data point term sent to Coder                                                                                                                                                        | System                             | 24 Aug 2020 12:10:24 |
| User entered 'fibromyelgia'                                                                                                                                                          | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:09:57 |

US3552140

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2008' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:09:57 |

US3552140

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:09:57 |

US3552140

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:09:57 |

US3552140

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:09:57 |

US3552140

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:09:57 |

US3552140

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2008' | System | 24 Aug 2020 12:09:57 |

US3552140

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2008' | System | 24 Aug 2020 12:09:57 |

US3552140

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:09:57 |

US3552140

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:09:57 |

US3552140

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:35:57

[Condition](#)

| Audit                                                                                                                                                                                                  | User                    | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0. | Coder Import (b) (4)    | 24 Aug 2020 12:11:29 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                           | Coder Import (b) (4)    | 24 Aug 2020 12:11:29 |
| Data point term sent to Coder                                                                                                                                                                          | System                  | 24 Aug 2020 12:10:24 |
| User entered 'insomnia'                                                                                                                                                                                | Stanley Doublin (b) (4) | 24 Aug 2020 12:10:14 |
|                                                                                                                                                                                                        | (b) (4)                 |                      |

US3552140

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2015' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:10:14 |

US3552140

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:10:14 |

US3552140

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:10:14 |

US3552140

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:10:14 |

US3552140

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:10:14 |

US3552140

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2015' | System | 24 Aug 2020 12:10:14 |

US3552140

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2015' | System | 24 Aug 2020 12:10:14 |

US3552140

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:10:14 |

US3552140

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:10:14 |

US3552140

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:35:57

[Condition](#)

| Audit                                                                                                                                                                        | User                   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0. | Coder Import (b) (4)   | 24 Aug 2020 12:12:32 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                 | Coder Import (b) (4)   | 24 Aug 2020 12:12:32 |
| Data point term sent to Coder                                                                                                                                                | System                 | 24 Aug 2020 12:11:26 |
| User entered 'seasonal allergies'                                                                                                                                            | Stanley Dublin (b) (4) | 24 Aug 2020 12:10:29 |

US3552140

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2000' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:10:29 |

US3552140

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:10:29 |

US3552140

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:10:29 |

US3552140

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:10:29 |

US3552140

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:10:29 |

US3552140

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 24 Aug 2020 12:10:29 |

**US3552140**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 24 Aug 2020 12:10:29 |

US3552140

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:10:29 |

US3552140

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:10:29 |

US3552140

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:35:57

Condition

| Audit                                                                                                                                                                                                                                         | User                                 | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\23.0.                             | Coder Import (b) (4)<br>(b) (4)      | 08 Oct 2020 10:30:33 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                                                                        | Coder Import (b) (4)<br>(b) (4)      | 08 Oct 2020 10:30:33 |
| 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)                     | 05 Oct 2020 10:53:48 |
| Data point term sent to Coder                                                                                                                                                                                                                 | System                               | 02 Oct 2020 18:57:20 |
| 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 'updated per query request' (Site from DM). | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 18:57:04 |
| Coding entries removed.                                                                                                                                                                                                                       | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 18:56:53 |
| User entered 'Elective GASTRIC BYPASS SURGERY' reason for change: Data Entry Error                                                                                                                                                            | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 18:56:53 |
| 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)                     | 25 Sep 2020 12:28:50 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\23.0.                             | Coder Import (b) (4)<br>(b) (4)      | 24 Aug 2020 12:12:32 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                   | Coder Import (b) (4)<br>(b) (4)      | 24 Aug 2020 12:12:32 |
| Data point term sent to Coder                                                                                                                                                                                                                 | System                               | 24 Aug 2020 12:11:25 |
| User entered 'gastric bypass surgery'                                                                                                                                                                                                         | Stanley Doublin (b) (4)<br>(b) (4)   | 24 Aug 2020 12:11:17 |

US3552140

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2000' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:11:17 |

US3552140

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:11:17 |

US3552140

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:35:57

[Condition ongoing at study entry](#)

| Audit                                                     | User                   | Time (GMT)           |
|-----------------------------------------------------------|------------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | Stanley Dublin (b) (4) | 24 Aug 2020 12:11:59 |
| User entered 'Yes (Y)'                                    | Stanley Dublin (b) (4) | 24 Aug 2020 12:11:17 |

US3552140

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                             | User                              | Time (GMT)           |
|-------------------------------------------------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2000' reason for change:<br>Data Entry Error | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:11:59 |
| User entered empty.                                               | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:11:17 |

US3552140

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:11:17 |

US3552140

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 24 Aug 2020 12:11:17 |

**US3552140**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 24 Aug 2020 12:11:17 |

US3552140

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 24 Aug 2020 12:11:59 |
| User entered empty.     | System | 24 Aug 2020 12:11:17 |

US3552140

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 24 Aug 2020 12:11:59 |
| User entered empty. | System | 24 Aug 2020 12:11:17 |

US3552140

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:35:57

[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)          | 06 Oct 2020 12:58:50 |
| 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 'updated' (Site from DM).          | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:28:33 |
| 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)          | 25 Sep 2020 12:29:14 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\23.0. | Coder Import (b) (4)      | 24 Aug 2020 12:13:34 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                            | Coder Import (b) (4)      | 24 Aug 2020 12:13:34 |
| Data point term sent to Coder                                                                                                                                                                                                          | System                    | 24 Aug 2020 12:12:27 |
| User entered 'cholestectomy'                                                                                                                                                                                                           | Stanley Doublin (b) (4)   | 24 Aug 2020 12:11:46 |

US3552140

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 1999' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:11:46 |

US3552140

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:11:46 |

US3552140

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:11:46 |

US3552140

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 1999' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:11:46 |

US3552140

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:11:46 |

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**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1999' | System | 24 Aug 2020 12:11:46 |

US3552140

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1999' | System | 24 Aug 2020 12:11:46 |

US3552140

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1999' | System | 24 Aug 2020 12:11:46 |

US3552140

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1999' | System | 24 Aug 2020 12:11:46 |

US3552140

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:35:57

[Condition](#)

| Audit                                                                                                                                                                                      | User                    | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\23.0. | Coder Import (b) (4)    | 25 Aug 2020 21:11:38 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                     | Coder Import (b) (4)    | 25 Aug 2020 21:11:38 |
| Data point term sent to Coder                                                                                                                                                              | System                  | 24 Aug 2020 12:13:27 |
| User entered 'borderline anemia'                                                                                                                                                           | Stanley Doublin (b) (4) | 24 Aug 2020 12:12:35 |
|                                                                                                                                                                                            | (b) (4)                 |                      |

US3552140

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 1979' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:12:35 |

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**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:12:35 |

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**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:12:35 |

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**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:12:35 |

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**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:12:35 |

US3552140

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1979' | System | 24 Aug 2020 12:12:35 |

US3552140

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1979' | System | 24 Aug 2020 12:12:35 |

US3552140

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:12:35 |

US3552140

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:12:35 |

US3552140

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:35:57

[Condition](#)

| Audit                                                                                                                                                                                         | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Thrombophlebitis, LLT: Thrombophlebitis - version MedDRA\\23.0. | Coder Import (b) (4)   | 24 Aug 2020 12:14:37 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                  | Coder Import (b) (4)   | 24 Aug 2020 12:14:37 |
| Data point term sent to Coder                                                                                                                                                                 | System                 | 24 Aug 2020 12:13:29 |
| User entered 'thrombophlebitis'                                                                                                                                                               | Stanley Dublin (b) (4) | 24 Aug 2020 12:13:16 |

US3552140

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2018' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:13:16 |

US3552140

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:13:16 |

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**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:13:16 |

US3552140

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2019' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:13:16 |

US3552140

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:13:16 |

US3552140

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2018' | System | 24 Aug 2020 12:13:16 |

US3552140

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2018' | System | 24 Aug 2020 12:13:16 |

US3552140

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2019' | System | 24 Aug 2020 12:13:16 |

US3552140

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2019' | System | 24 Aug 2020 12:13:16 |

US3552140

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:35:57

[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)          | 06 Oct 2020 12:57:36 |
| 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 'updated' (Site from DM).                        | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:33:09 |
| 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)          | 25 Sep 2020 12:29:22 |
| 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 fusion surgery, LLT: Spinal fusion - version MedDRA\23.0. | Coder Import (b) (4)      | 24 Aug 2020 12:15:38 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                          | Coder Import (b) (4)      | 24 Aug 2020 12:15:38 |
| Data point term sent to Coder                                                                                                                                                                                                                        | System                    | 24 Aug 2020 12:14:30 |
| User entered 'spinal fusion'                                                                                                                                                                                                                         | Stanley Dublin (b) (4)    | 24 Aug 2020 12:13:38 |

US3552140

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un Jan 2019' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:13:38 |

US3552140

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:13:38 |

US3552140

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:13:38 |

US3552140

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un Jan 2019' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:13:38 |

US3552140

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:35:57

[Stop date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:13:38 |

US3552140

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2019' | System | 24 Aug 2020 12:13:38 |

US3552140

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2019' | System | 24 Aug 2020 12:13:38 |

US3552140

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2019' | System | 24 Aug 2020 12:13:38 |

US3552140

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2019' | System | 24 Aug 2020 12:13:38 |

US3552140

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:35:57

[Condition](#)

| Audit                                                                                                                                                         | User                    | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0. | Coder Import (b) (4)    | 24 Aug 2020 12:16:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                  | Coder Import (b) (4)    | 24 Aug 2020 12:16:43 |
| Data point term sent to Coder                                                                                                                                 | System                  | 24 Aug 2020 12:15:31 |
| User entered 'menopause'                                                                                                                                      | Stanley Doublin (b) (4) | 24 Aug 2020 12:15:05 |

US3552140

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2013' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:15:05 |

US3552140

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:15:05 |

US3552140

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:15:05 |

US3552140

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2013' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:15:05 |

US3552140

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:15:05 |

US3552140

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2013' | System | 24 Aug 2020 12:15:05 |

US3552140

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2013' | System | 24 Aug 2020 12:15:05 |

US3552140

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2013' | System | 24 Aug 2020 12:15:05 |

US3552140

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2013' | System | 24 Aug 2020 12:15:05 |

US3552140

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:35:57

Condition

| Audit                                                                                                                                                                                                                                         | User                                 | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.                            | Coder Import (b) (4)<br>(b) (4)      | 17 Nov 2020 13:31:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                                                                        | Coder Import (b) (4)<br>(b) (4)      | 17 Nov 2020 13:31:46 |
| 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)                     | 06 Oct 2020 12:46:01 |
| 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 'updated per query request' (Site from DM). | Cassandra Zehenny (b) (4)<br>(b) (4) | 01 Oct 2020 19:35:18 |
| Data point term sent to Coder                                                                                                                                                                                                                 | System                               | 01 Oct 2020 19:35:15 |
| Coding entries removed.                                                                                                                                                                                                                       | Cassandra Zehenny (b) (4)<br>(b) (4) | 01 Oct 2020 19:35:03 |
| User entered 'LEFT KNEE REPLACEMENT secondary to rheumatoid arthritis' reason for change: Per Query Resolution                                                                                                                                | Cassandra Zehenny (b) (4)<br>(b) (4) | 01 Oct 2020 19:35:03 |
| 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)                     | 25 Sep 2020 12:29:48 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.                            | Coder Import (b) (4)<br>(b) (4)      | 24 Aug 2020 12:16:44 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                   | Coder Import (b) (4)<br>(b) (4)      | 24 Aug 2020 12:16:44 |
| Data point term sent to Coder                                                                                                                                                                                                                 | System                               | 24 Aug 2020 12:15:34 |
| User entered 'left knee replacement'                                                                                                                                                                                                          | Stanley Doublin (b) (4)<br>(b) (4)   | 24 Aug 2020 12:15:31 |

US3552140

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2018' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:15:31 |

US3552140

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:15:31 |

US3552140

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:15:31 |

US3552140

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2018' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:15:31 |

US3552140

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:35:57

[Stop date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:15:31 |

US3552140

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2018' | System | 24 Aug 2020 12:15:31 |

US3552140

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2018' | System | 24 Aug 2020 12:15:31 |

US3552140

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2018' | System | 24 Aug 2020 12:15:31 |

US3552140

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2018' | System | 24 Aug 2020 12:15:31 |

US3552140

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:35:57

[Condition](#)

| Audit                                                                                                                                                                                                                                                                       | User                              | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Connective tissue disorders (excl congenital), HLT: Connective tissue disorders NEC, PT: Mixed connective tissue disease, LLT: Mixed connective tissue disease - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)   | 24 Nov 2020 12:14:22 |
| 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 Nov 2020 12:14:22 |
| Data point term sent to Coder                                                                                                                                                                                                                                               | System                            | 24 Aug 2020 19:02:26 |
| User entered 'MIXED CONNECTIVE disease' reason for change: Data Entry Error                                                                                                                                                                                                 | Heather Douds (b) (4)<br>(b) (4)  | 24 Aug 2020 19:01:42 |
| Data point term sent to Coder                                                                                                                                                                                                                                               | System                            | 24 Aug 2020 12:16:35 |
| User entered 'mixed connective'                                                                                                                                                                                                                                             | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:15:53 |

US3552140

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un Sep 2004' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:15:53 |

US3552140

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:15:53 |

US3552140

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:15:53 |

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**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:15:53 |

US3552140

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:15:53 |

US3552140

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Sep 2004' | System | 24 Aug 2020 12:15:53 |

US3552140

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2004' | System | 24 Aug 2020 12:15:53 |

US3552140

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:15:53 |

US3552140

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:15:53 |

US3552140

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:35:57

[Condition](#)

| Audit                                                                                                                                                                                                                                                                    | User                               | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Raynaud's phenomenon, LLT: Raynaud's disease - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)    | 24 Aug 2020 12:18:30 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                                                             | Coder Import (b) (4)<br>(b) (4)    | 24 Aug 2020 12:18:30 |
| Data point term sent to Coder                                                                                                                                                                                                                                            | System                             | 24 Aug 2020 12:17:37 |
| User entered 'raynaud's disease'                                                                                                                                                                                                                                         | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:16:40 |

US3552140

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un Sep 2004' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:16:40 |

US3552140

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:16:40 |

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:35:57

[Condition ongoing at study entry](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:16:40 |

US3552140

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:16:40 |

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**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:16:40 |

US3552140

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Sep 2004' | System | 24 Aug 2020 12:16:40 |

US3552140

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2004' | System | 24 Aug 2020 12:16:40 |

US3552140

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:16:40 |

US3552140

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:16:40 |

US3552140

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:35:57

[Condition](#)

| Audit                                                                                                                                                                                           | User                              | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema, LLT: Pitting edema - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)   | 24 Aug 2020 19:29:38 |
| 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 Aug 2020 19:29:38 |
| Data point term sent to Coder                                                                                                                                                                   | System                            | 24 Aug 2020 12:17:38 |
| User entered 'bilateral pitting edema'                                                                                                                                                          | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:17:30 |

US3552140

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2012' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:17:30 |

US3552140

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:17:30 |

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**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:17:30 |

US3552140

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:17:30 |

US3552140

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:17:30 |

US3552140

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2012' | System | 24 Aug 2020 12:17:30 |

US3552140

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2012' | System | 24 Aug 2020 12:17:30 |

US3552140

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:17:30 |

US3552140

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:17:30 |

US3552140

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:35:57

[Condition](#)

| Audit                                                                                                                                                               | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0. | Coder Import (b) (4)  | 10 Sep 2020 15:13:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                        | Coder Import (b) (4)  | 10 Sep 2020 15:13:43 |
| Data point term sent to Coder                                                                                                                                       | System                | 10 Sep 2020 15:13:10 |
| User entered 'Anxiety'                                                                                                                                              | Heather Douds (b) (4) | 10 Sep 2020 15:12:56 |
|                                                                                                                                                                     | (b) (4)               |                      |

US3552140

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered 'un Apr 2019' | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:12:56 |

US3552140

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:12:56 |

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**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:12:56 |

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**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:12:56 |

US3552140

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:12:56 |

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**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Apr 2019' | System | 10 Sep 2020 15:12:56 |

US3552140

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2019' | System | 10 Sep 2020 15:12:56 |

US3552140

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:35:57

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Sep 2020 15:12:56 |

US3552140

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Sep 2020 15:12:56 |

US3552140

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:35:57

[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)          | 13 Oct 2020 11:05:36 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Corneal implant, LLT: Corneal implant - version MedDRA\23.0. | Coder Import (b) (4)      | 09 Oct 2020 11:47:29 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                                             | (b) (4)                   | 09 Oct 2020 11:47:29 |
| Data point term sent to Coder                                                                                                                                                                                      | System                    | 02 Oct 2020 19:02:33 |
| Coding entries removed.                                                                                                                                                                                            | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:01:40 |
| User entered 'BILATERAL CORNEAL intacs' reason for change: New Information                                                                                                                                         | (b) (4)                   |                      |
| 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).                | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:01:40 |
| ' answered with 'will ask subject and update data once received' (Site from DM).                                                                                                                                   | (b) (4)                   |                      |
| 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).    | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:38:06 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Corneal implant, LLT: Corneal implant - version MedDRA\23.0. | (b) (4), (b) (6)          | 25 Sep 2020 12:32:15 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                                             | Coder Import (b) (4)      | 13 Sep 2020 05:15:43 |
| Data point term sent to Coder                                                                                                                                                                                      | (b) (4)                   |                      |
| User entered 'bilateral corneal rings'                                                                                                                                                                             | System                    | 12 Sep 2020 15:30:04 |
|                                                                                                                                                                                                                    | Heather Douds (b) (4)     | 12 Sep 2020 15:29:06 |
|                                                                                                                                                                                                                    | (b) (4)                   |                      |

US3552140

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| User entered 'un UNK 1994' | Heather Douds (b) (4)<br>(b) (4) | 12 Sep 2020 15:29:06 |

US3552140

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Heather Douds (b) (4)<br>(b) (4) | 12 Sep 2020 15:29:06 |

US3552140

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Heather Douds (b) (4)<br>(b) (4) | 12 Sep 2020 15:29:06 |

US3552140

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 12 Sep 2020 15:29:06 |

US3552140

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                             | Time (GMT)           |
|------------------|----------------------------------|----------------------|
| User entered '0' | Heather Douds (b) (4)<br>(b) (4) | 12 Sep 2020 15:29:06 |

US3552140

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1994' | System | 12 Sep 2020 15:29:06 |

US3552140

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1994' | System | 12 Sep 2020 15:29:06 |

US3552140

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Sep 2020 15:29:06 |

US3552140

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Sep 2020 15:29:06 |

US3552140

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:35:57

[Condition](#)

| Audit                                                                                                                                                                                      | User                      | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0. | Coder Import (b) (4)      | 01 Oct 2020 19:31:47 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                               | Coder Import (b) (4)      | 01 Oct 2020 19:31:47 |
| Data point term sent to Coder                                                                                                                                                              | System                    | 01 Oct 2020 19:31:04 |
| User entered 'cholelithiasis'                                                                                                                                                              | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:30:51 |
|                                                                                                                                                                                            | (b) (4)                   |                      |

US3552140

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| User entered empty. | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:30:51 |
|                     | (b) (4)                   |                      |

US3552140

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                      | Time (GMT)           |
|------------------|---------------------------|----------------------|
| User entered '1' | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:30:51 |
|                  | (b) (4)                   |                      |

US3552140

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                 | User                      | Time (GMT)           |
|-----------------------|---------------------------|----------------------|
| User entered 'No (N)' | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:30:51 |
|                       | (b) (4)                   |                      |

US3552140

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                      | Time (GMT)           |
|----------------------------|---------------------------|----------------------|
| User entered 'un UNK 1999' | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:30:51 |
|                            | (b) (4)                   |                      |

US3552140

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                      | Time (GMT)           |
|------------------|---------------------------|----------------------|
| User entered '0' | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:30:51 |
|                  | (b) (4)                   |                      |

US3552140

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Oct 2020 19:30:51 |

US3552140

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Oct 2020 19:30:51 |

US3552140

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1999' | System | 01 Oct 2020 19:30:51 |

US3552140

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1999' | System | 01 Oct 2020 19:30:51 |

US3552140

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:35:57

[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 protrusion, LLT: Lumbar disc herniation - version MedDRA\\23.0. | Coder Import (b) (4)      | 02 Oct 2020 05:31:39 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                                                                                                                      | Coder Import (b) (4)      | 02 Oct 2020 05:31:39 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                | System                    | 01 Oct 2020 19:34:13 |
| User entered 'herniated discs L3-L5'                                                                                                                                                                                                                                                                         | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:33:55 |
|                                                                                                                                                                                                                                                                                                              | (b) (4)                   |                      |

US3552140

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| User entered empty. | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:33:55 |
|                     | (b) (4)                   |                      |

US3552140

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit            | User                      | Time (GMT)           |
|------------------|---------------------------|----------------------|
| User entered '1' | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:33:55 |
|                  | (b) (4)                   |                      |

US3552140

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 26 Nov 2020 09:35:57**

[Condition ongoing at study entry](#)

| Audit                 | User                      | Time (GMT)           |
|-----------------------|---------------------------|----------------------|
| User entered 'No (N)' | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:33:55 |
|                       | (b) (4)                   |                      |

US3552140

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                      | Time (GMT)           |
|----------------------------|---------------------------|----------------------|
| User entered 'un Jan 2019' | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:33:55 |
|                            | (b) (4)                   |                      |

US3552140

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 26 Nov 2020 09:35:57**

[Stop date completely unknown](#)

| Audit            | User                      | Time (GMT)           |
|------------------|---------------------------|----------------------|
| User entered '0' | Cassandra Zehenny (b) (4) | 01 Oct 2020 19:33:55 |
|                  | (b) (4)                   |                      |

US3552140

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Oct 2020 19:33:55 |

US3552140

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Oct 2020 19:33:55 |

US3552140

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2019' | System | 01 Oct 2020 19:33:55 |

US3552140

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2019' | System | 01 Oct 2020 19:33:55 |

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

[Were vital signs assessed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:19:15 |

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '22 Aug 2020' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:19:15 |

US3552140

**Folder:** Screening

**Form:** Vital Signs

**Generated On:** 26 Nov 2020 09:35:57

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '11:32' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:19:15 |

US3552140

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:32' | System | 24 Aug 2020 12:19:15 |

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '66.5' in    | Stanley Dublin (b) (4) | 24 Aug 2020 12:19:15 |
| DataPoint set to visible. | (b) (4)<br>System      | 22 Aug 2020 18:05:11 |

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '280' lb     | Stanley Dublin (b) (4) | 24 Aug 2020 12:19:15 |
| DataPoint set to visible. | (b) (4)<br>System      | 22 Aug 2020 18:05:11 |

**US3552140**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:57**

**BMI (xxx.x)**

| Audit                                      | User   | Time (GMT)           |
|--------------------------------------------|--------|----------------------|
| Amendment Manager: User entered '44.60922' | System | 17 Sep 2020 00:20:10 |
| User entered '44.6'                        | System | 24 Aug 2020 12:19:15 |
| DataPoint set to visible.                  | System | 22 Aug 2020 18:05:11 |

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

[BMI units](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered 'kg/m2'      | System | 24 Aug 2020 12:19:15 |
| DataPoint set to visible. | System | 22 Aug 2020 18:05:11 |

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

Temperature (xxx.x)

| Audit                                    | User                               | Time (GMT)           |
|------------------------------------------|------------------------------------|----------------------|
| User entered missing code ND - Not Done. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:19:15 |

US3552140

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:57**

[Route of measurement](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:19:15 |

US3552140

**Folder:** Screening

**Form:** Vital Signs

**Generated On:** 26 Nov 2020 09:35:57

[If Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:19:15 |

US3552140

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:57**

[Pulse \(xxx\)](#)

| Audit                                    | User                              | Time (GMT)           |
|------------------------------------------|-----------------------------------|----------------------|
| User entered missing code ND - Not Done. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:19:15 |

US3552140

**Folder:** Screening

**Form:** Vital Signs

**Generated On:** 26 Nov 2020 09:35:57

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 24 Aug 2020 12:19:15 |

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                    | User                              | Time (GMT)           |
|------------------------------------------|-----------------------------------|----------------------|
| User entered missing code ND - Not Done. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:19:15 |

US3552140

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:57**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 24 Aug 2020 12:19:15 |

US3552140

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                                    | User                              | Time (GMT)           |
|------------------------------------------|-----------------------------------|----------------------|
| User entered missing code ND - Not Done. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:19:15 |

US3552140

**Folder:** Screening

**Form:** Vital Signs

**Generated On:** 26 Nov 2020 09:35:57

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Aug 2020 12:19:15 |

US3552140

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                                    | User                              | Time (GMT)           |
|------------------------------------------|-----------------------------------|----------------------|
| User entered missing code ND - Not Done. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:19:15 |

US3552140

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:35:57**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Aug 2020 12:19:15 |

US3552140

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:35:57**

[Was the physical examination performed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:19:39 |

US3552140

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '22 Aug 2020' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:19:39 |

US3552140

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:35:57**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '22 Aug 2020' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:20:32 |

US3552140

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:20:32 |

US3552140

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:57

If No, [what is the reason?](#)

| Audit                                                                                                                                                                                                                                                                                                           | User                               | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User closed query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).                               | (b) (4), (b) (6)                   | 08 Sep 2020 06:18:05 |
| Query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' answered with 'updated per query request' (Site from DM). | Heather Douds (b) (4)<br>(b) (4)   | 04 Sep 2020 15:04:27 |
| User opened query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).                               | (b) (4), (b) (6)                   | 04 Sep 2020 08:58:39 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)'                                                                                                                                                                                                                                                                | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:20:32 |

US3552140

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:35:57**

[If Partner medically sterile or Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:20:32 |

US3552140

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:20:32 |

US3552140

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:35:57**

[Date of surgery unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:20:32 |

US3552140

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'un UNK 2013' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:20:32 |

US3552140

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 09:35:57**

[Date of last menstruation unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:20:32 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

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

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

**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)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

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

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

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

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

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

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

**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)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

**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)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

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

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

**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)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

[Other](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

[Specify](#)

| Audit                                                            | User                              | Time (GMT)           |
|------------------------------------------------------------------|-----------------------------------|----------------------|
| User entered 'out in community, grocery shopping, family visits' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

No Risk Identified

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

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

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

**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' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

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

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

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' | Stanley Doublin (b) (4) | 24 Aug 2020 12:22:30 |
|                  | (b) (4)                 |                      |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

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

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

[Other](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:57

[Specify](#)

| Audit                                                                                              | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User entered 'GRANDCHILD VISITS<br>FREQUENTLY - 7 YEAR OLD' reason for change:<br>Data Entry Error | Stanley Dublin (b) (4) | 24 Aug 2020 12:23:02 |
| User entered 'grandchildred visits frequently - 7 year<br>old'                                     | Stanley Dublin (b) (4) | 24 Aug 2020 12:22:30 |

US3552140

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:57

[Was this visit performed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:23:13 |

US3552140

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:57

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '22 Aug 2020' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:23:13 |

US3552140

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:57

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

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:23:13 |

US3552140

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:35:57**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 24 Aug 2020 12:23:13 |

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:57

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

| Audit                      | User                                            | Time (GMT)           |
|----------------------------|-------------------------------------------------|----------------------|
| User entered '22 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 22 Aug 2020 18:04:17 |

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:57

[What was the participant's randomization number?](#)

| Audit                 | User                                            | Time (GMT)           |
|-----------------------|-------------------------------------------------|----------------------|
| User entered '144697' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 22 Aug 2020 18:04:17 |

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:57

[In what Cohort was the participant enrolled?](#)

| Audit                                             | User                                           | Time (GMT)           |
|---------------------------------------------------|------------------------------------------------|----------------------|
| User entered '>=18 and <65 years and at risk (2)' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 22 Aug 2020 18:04:17 |

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:57

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)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:23:26 |

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:57

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

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:23:26 |

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:57

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

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:23:26 |

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:57

Diabetes (Type I, Type 2, or gestational)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:23:26 |

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:57

[Liver Disease](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:23:26 |

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                        | User                   | Time (GMT)           |
|----------------------------------------------|------------------------|----------------------|
| User entered 'No (N)'                        | Stanley Dublin (b) (4) | 21 Sep 2020 17:22:17 |
| Amendment Manager: DataPoint set to visible. | (b) (4)                | 19 Sep 2020 10:39:19 |
| Amendment Manager inserted this DataPoint.   | System                 | 19 Sep 2020 02:20:44 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:57

Height

| Audit                                    | User                              | Time (GMT)           |
|------------------------------------------|-----------------------------------|----------------------|
| User entered missing code ND - Not Done. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:57

Weight

| Audit                                    | User                              | Time (GMT)           |
|------------------------------------------|-----------------------------------|----------------------|
| User entered missing code ND - Not Done. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:57

Height

| Audit                                    | User                              | Time (GMT)           |
|------------------------------------------|-----------------------------------|----------------------|
| User entered missing code ND - Not Done. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:57

Weight

| Audit                                    | User                              | Time (GMT)           |
|------------------------------------------|-----------------------------------|----------------------|
| User entered missing code ND - Not Done. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

[Timepoint](#)

| Audit                                            | User                              | Time (GMT)           |
|--------------------------------------------------|-----------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

[Were vital signs assessed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '22 Aug 2020' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                    | User                   | Time (GMT)           |
|----------------------------------------------------------|------------------------|----------------------|
| User entered '11:32' reason for change: Data Entry Error | Heather Douds (b) (4)  | 24 Aug 2020 19:49:40 |
| User entered '12:32'                                     | Stanley Dublin (b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:32' | System | 24 Aug 2020 19:49:40 |
| User entered '22 Aug 2020 12:32' | System | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

Temperature (xxx.x)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered '98.3' F | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

[Route of measurement](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (Oral)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

[If Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

[Pulse \(xxx\)](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '90' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

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

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '16' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

Systolic Blood Pressure (xxx)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '131' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

Diastolic Blood Pressure (xxx)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '91' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:57

Height

| Audit                                    | User                              | Time (GMT)           |
|------------------------------------------|-----------------------------------|----------------------|
| User entered missing code ND - Not Done. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:57

[Weight](#)

| Audit                                    | User                              | Time (GMT)           |
|------------------------------------------|-----------------------------------|----------------------|
| User entered missing code ND - Not Done. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:24:50 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

[Timepoint](#)

| Audit                                              | User                              | Time (GMT)           |
|----------------------------------------------------|-----------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:25:23 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

[Were vital signs assessed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:25:23 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '22 Aug 2020' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:25:23 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '14:04' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:25:23 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 14:04' | System | 24 Aug 2020 12:25:23 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

Temperature (xxx.x)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered '98.3' F | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:25:23 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

[Route of measurement](#)

| Audit                                                                                        | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System                 | 24 Aug 2020 12:25:30 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                        | 24 Aug 2020 12:25:30 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error                               | Stanley Dublin (b) (4) | 24 Aug 2020 12:25:30 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                 | 24 Aug 2020 12:25:23 |
| User entered empty.                                                                          | Stanley Dublin (b) (4) | 24 Aug 2020 12:25:23 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

[If Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:25:23 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

[Pulse \(xxx\)](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '90' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:25:23 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 24 Aug 2020 12:25:23 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

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

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '18' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:25:23 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 24 Aug 2020 12:25:23 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

Systolic Blood Pressure (xxx)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '136' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:25:23 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Aug 2020 12:25:23 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

Diastolic Blood Pressure (xxx)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '94' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:25:23 |

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Aug 2020 12:25:23 |

US3552140

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:57

[Was the physical examination performed?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:25:40 |

US3552140

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:57

Date of examination (*dd MMM yyyy*)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:25:40 |

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

[Was study treatment given?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Aug 2020 18:41:00 |
|                        |                  |                      |

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

[If No, reason not given](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 22 Aug 2020 18:41:00 |
|                     |                  |                      |

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 22 Aug 2020 18:41:00 |
|                     |                  |                      |

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 22 Aug 2020 18:41:00 |

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

What was the treatment date? (dd MMM yyyy)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '22 Aug 2020' | (b) (4), (b) (6) | 22 Aug 2020 18:41:00 |
|                            |                  |                      |

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                                                                                   | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System           | 22 Aug 2020 18:41:13 |
| User entered '13:34' reason for change: Data Entry Error                                | (b) (4), (b) (6) | 22 Aug 2020 18:41:13 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System           | 22 Aug 2020 18:41:00 |
| User entered '13:' (non-conformant).                                                    | (b) (4), (b) (6) | 22 Aug 2020 18:41:00 |

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

[Treatment Date and Time \(derived\)](#)

| Audit                                            | User   | Time (GMT)           |
|--------------------------------------------------|--------|----------------------|
| User entered '22 Aug 2020 13:34'                 | System | 22 Aug 2020 18:41:13 |
| User entered '22 Aug 2020 13:' (non-conformant). | System | 22 Aug 2020 18:41:00 |

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

[Which arm was used to give treatment?](#)

| Audit                                | User             | Time (GMT)           |
|--------------------------------------|------------------|----------------------|
| User entered 'Right Arm (RIGHT ARM)' | (b) (4), (b) (6) | 22 Aug 2020 18:41:00 |
|                                      |                  |                      |

US3552140

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:35:57**

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 22 Aug 2020 18:41:00 |

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 22 Aug 2020 18:41:00 |

US3552140

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:57

[Was the sample collected?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:26:02 |

US3552140

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:57

Collection date (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '22 Aug 2020' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:26:02 |

US3552140

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:57

Collection time (00:00-23:59)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '12:50' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:26:02 |

US3552140

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:57

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:50' | System | 24 Aug 2020 12:26:02 |

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:35:57

Collection date (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '22 Aug 2020' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:26:18 |

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:57

[Lab Test](#)

| Audit                                                        | User                   | Time (GMT)           |
|--------------------------------------------------------------|------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Stanley Dublin (b) (4) | 24 Aug 2020 12:26:18 |

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:57

[Was the sample collected?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:26:18 |

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:57

Collection time (00:00 - 23:59)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '12:55' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:26:18 |

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:55' | System | 24 Aug 2020 12:26:18 |

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:57

[Lab Test](#)

| Audit                                                        | User                   | Time (GMT)           |
|--------------------------------------------------------------|------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Stanley Dublin (b) (4) | 24 Aug 2020 12:26:22 |

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:57

[Was the sample collected?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:26:22 |

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:57

Collection time (00:00 - 23:59)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:26:22 |

**US3552140**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:26:22 |

US3552140

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

[Is the participant continuing to the next visit?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Mikayla Frye (b) (4)<br>(b) (4) | 29 Aug 2020 19:55:13 |

US3552140

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Aug 2020 19:55:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:08:14', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aafa6290-5ac0-4816-b507-ed90d9645df5' | System | 22 Aug 2020 19:08:36 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 22 Aug 2020 19:08:36 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:08:21', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aafa6290-5ac0-4816-b507-ed90d9645df5' | System | 22 Aug 2020 19:08:36 |
| User entered '98.3'                                                                                                                                                                                                                        | System | 22 Aug 2020 19:08:36 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:08:27', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aafa6290-5ac0-4816-b507-ed90d9645df5' | System | 22 Aug 2020 19:08:36 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 22 Aug 2020 19:08:36 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:08:33', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aafa6290-5ac0-4816-b507-ed90d9645df5' | System | 22 Aug 2020 19:08:36 |
| User entered '22 Aug 2020 14:08'                                                                                                                                                                                                           | System | 22 Aug 2020 19:08:36 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 13:54' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 16:24' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 1, after vaccination (at home)' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:17:49', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d59ebb8-c835-49c5-8c28-755c81d0c9df' | System | 23 Aug 2020 02:18:10 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 23 Aug 2020 02:18:10 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

Please record your **TEMPERATURE in °F**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:17:57', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d59ebb8-c835-49c5-8c28-755c81d0c9df' | System | 23 Aug 2020 02:18:10 |
| User entered '97.8'                                                                                                                                                                                                                        | System | 23 Aug 2020 02:18:10 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:01', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d59ebb8-c835-49c5-8c28-755c81d0c9df' | System | 23 Aug 2020 02:18:10 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 23 Aug 2020 02:18:10 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:06', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d59ebb8-c835-49c5-8c28-755c81d0c9df' | System | 23 Aug 2020 02:18:10 |
| User entered '22 Aug 2020 21:18'                                                                                                                                                                                                           | System | 23 Aug 2020 02:18:10 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 17:19' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 2' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:57

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:11:41', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '179918e4-5550-48e6-b62e-21f8b0de1769' | System | 24 Aug 2020 02:12:04 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 24 Aug 2020 02:12:04 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:57

Please record your **TEMPERATURE in °F**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:11:49', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '179918e4-5550-48e6-b62e-21f8b0de1769' | System | 24 Aug 2020 02:12:04 |
| User entered '97.8'                                                                                                                                                                                                                        | System | 24 Aug 2020 02:12:04 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:11:52', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '179918e4-5550-48e6-b62e-21f8b0de1769' | System | 24 Aug 2020 02:12:04 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 24 Aug 2020 02:12:04 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:11:58', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '179918e4-5550-48e6-b62e-21f8b0de1769' | System | 24 Aug 2020 02:12:04 |
| User entered '23 Aug 2020 21:11'                                                                                                                                                                                                           | System | 24 Aug 2020 02:12:04 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:35:57

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 3' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:57

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:04', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '174fe3da-5840-486c-a5ad-08dee4613e1b' | System | 25 Aug 2020 01:40:21 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 25 Aug 2020 01:40:21 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:57

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:11', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '174fe3da-5840-486c-a5ad-08dee4613e1b' | System | 25 Aug 2020 01:40:21 |
| User entered '97.2'                                                                                                                                                                                                                        | System | 25 Aug 2020 01:40:21 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:14', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '174fe3da-5840-486c-a5ad-08dee4613e1b' | System | 25 Aug 2020 01:40:21 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 25 Aug 2020 01:40:21 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:35:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:18', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '174fe3da-5840-486c-a5ad-08dee4613e1b' | System | 25 Aug 2020 01:40:21 |
| User entered '24 Aug 2020 20:40'                                                                                                                                                                                                           | System | 25 Aug 2020 01:40:21 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 4' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:35:57

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:41:37', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '00753a79-26dd-46d9-adad-4d78119493a5' | System | 26 Aug 2020 10:42:09 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 26 Aug 2020 10:42:09 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:35:57

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:41:57', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '00753a79-26dd-46d9-adad-4d78119493a5' | System | 26 Aug 2020 10:42:09 |
| User entered '97.7'                                                                                                                                                                                                                        | System | 26 Aug 2020 10:42:09 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:01', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '00753a79-26dd-46d9-adad-4d78119493a5' | System | 26 Aug 2020 10:42:09 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 26 Aug 2020 10:42:09 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:35:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:04', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '00753a79-26dd-46d9-adad-4d78119493a5' | System | 26 Aug 2020 10:42:09 |
| User entered '26 Aug 2020 05:42'                                                                                                                                                                                                           | System | 26 Aug 2020 10:42:09 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 5' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:57

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:43:30', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd5d7f432-ebba-4c94-ac95-3a475d640d7d' | System | 27 Aug 2020 04:44:02 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 27 Aug 2020 04:44:02 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:57

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:43:50', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd5d7f432-ebba-4c94-ac95-3a475d640d7d' | System | 27 Aug 2020 04:44:02 |
| User entered '97.9'                                                                                                                                                                                                                        | System | 27 Aug 2020 04:44:02 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:43:54', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd5d7f432-ebba-4c94-ac95-3a475d640d7d' | System | 27 Aug 2020 04:44:02 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 27 Aug 2020 04:44:02 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:43:57', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd5d7f432-ebba-4c94-ac95-3a475d640d7d' | System | 27 Aug 2020 04:44:02 |
| User entered '26 Aug 2020 23:43'                                                                                                                                                                                                           | System | 27 Aug 2020 04:44:02 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:35:57

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 6' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:57

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:06', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd358dc2a-99c2-416c-8ddf-a28b418edc4b' | System | 28 Aug 2020 08:35:31 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 28 Aug 2020 08:35:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:57

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:17', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd358dc2a-99c2-416c-8ddf-a28b418edc4b' | System | 28 Aug 2020 08:35:31 |
| User entered '96.6'                                                                                                                                                                                                                        | System | 28 Aug 2020 08:35:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:20', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd358dc2a-99c2-416c-8ddf-a28b418edc4b' | System | 28 Aug 2020 08:35:31 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 28 Aug 2020 08:35:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:24', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd358dc2a-99c2-416c-8ddf-a28b418edc4b' | System | 28 Aug 2020 08:35:31 |
| User entered '28 Aug 2020 03:35'                                                                                                                                                                                                           | System | 28 Aug 2020 08:35:31 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:35:57

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 7' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:57

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:23:32', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3ef53b37-0288-414b-93fb-6ddaa8496977' | System | 29 Aug 2020 05:23:49 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 29 Aug 2020 05:23:49 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:57

Please record your **TEMPERATURE in °F**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:23:39', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3ef53b37-0288-414b-93fb-6ddaa8496977' | System | 29 Aug 2020 05:23:49 |
| User entered '97.6'                                                                                                                                                                                                                        | System | 29 Aug 2020 05:23:49 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:23:44', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3ef53b37-0288-414b-93fb-6ddaa8496977' | System | 29 Aug 2020 05:23:49 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 29 Aug 2020 05:23:49 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:23:46', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3ef53b37-0288-414b-93fb-6ddaa8496977' | System | 29 Aug 2020 05:23:49 |
| User entered '29 Aug 2020 00:23'                                                                                                                                                                                                           | System | 29 Aug 2020 05:23:49 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:57

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:35:57

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-22T14:08:43', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '79a0bdd1-d8ef-4682-9c1a-231d3119f788' | System | 22 Aug 2020 19:09:01 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 22 Aug 2020 19:09:01 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:08:47', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '79a0bdd1-d8ef-4682-9c1a-231d3119f788' | System | 22 Aug 2020 19:09:01 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 22 Aug 2020 19:09:01 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:08:51', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '79a0bdd1-d8ef-4682-9c1a-231d3119f788' | System | 22 Aug 2020 19:09:01 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 22 Aug 2020 19:09:01 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-22T14:08:55', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '79a0bdd1-d8ef-4682-9c1a-231d3119f788' | System | 22 Aug 2020 19:09:01 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 22 Aug 2020 19:09:01 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '79a0bdd1-d8ef-4682-9c1a-231d3119f788' | System | 22 Aug 2020 19:09:01 |
| User entered '22 Aug 2020 14:09'                                                                                                                                                                                                           | System | 22 Aug 2020 19:09:01 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 13:54' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 16:24' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 1, after vaccination (at home)' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:34', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5a9a960f-efcf-48b9-86c1-e0a20acc6c96' | System | 23 Aug 2020 02:18:51 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 23 Aug 2020 02:18:51 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:37', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5a9a960f-efcf-48b9-86c1-e0a20acc6c96' | System | 23 Aug 2020 02:18:51 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 23 Aug 2020 02:18:51 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:41', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5a9a960f-efcf-48b9-86c1-e0a20acc6c96' | System | 23 Aug 2020 02:18:51 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 23 Aug 2020 02:18:51 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:44', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5a9a960f-efcf-48b9-86c1-e0a20acc6c96' | System | 23 Aug 2020 02:18:51 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 23 Aug 2020 02:18:51 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:47', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5a9a960f-efcf-48b9-86c1-e0a20acc6c96' | System | 23 Aug 2020 02:18:51 |
| User entered '22 Aug 2020 21:18'                                                                                                                                                                                                           | System | 23 Aug 2020 02:18:51 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 17:19' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 2' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-23T21:12:30', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'afcea38a-d286-4330-9033-18f2045f0bed' | System | 24 Aug 2020 02:14:05 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 24 Aug 2020 02:14:05 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:57

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:12:51', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'afcea38a-d286-4330-9033-18f2045f0bed' | System | 24 Aug 2020 02:14:05 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 24 Aug 2020 02:14:05 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:09', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'afcea38a-d286-4330-9033-18f2045f0bed' | System | 24 Aug 2020 02:14:05 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 24 Aug 2020 02:14:05 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:12', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'afcea38a-d286-4330-9033-18f2045f0bed' | System | 24 Aug 2020 02:14:05 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 24 Aug 2020 02:14:05 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:35:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:16', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'afcea38a-d286-4330-9033-18f2045f0bed' | System | 24 Aug 2020 02:14:05 |
| User entered '23 Aug 2020 21:13'                                                                                                                                                                                                           | System | 24 Aug 2020 02:14:05 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 3' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:40', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '2ef3b729-0d81-485a-be6b-b67f4d919497' | System | 25 Aug 2020 01:41:02 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 25 Aug 2020 01:41:02 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:57

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:43', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '2ef3b729-0d81-485a-be6b-b67f4d919497' | System | 25 Aug 2020 01:41:02 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 25 Aug 2020 01:41:02 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:46', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '2ef3b729-0d81-485a-be6b-b67f4d919497' | System | 25 Aug 2020 01:41:02 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 25 Aug 2020 01:41:02 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:55', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '2ef3b729-0d81-485a-be6b-b67f4d919497' | System | 25 Aug 2020 01:41:02 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 25 Aug 2020 01:41:02 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:35:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:58', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '2ef3b729-0d81-485a-be6b-b67f4d919497' | System | 25 Aug 2020 01:41:02 |
| User entered '24 Aug 2020 20:40'                                                                                                                                                                                                           | System | 25 Aug 2020 01:41:02 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 4' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:10', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '29b7b93a-5528-4697-b43d-7a07cd05ecbd' | System | 26 Aug 2020 10:42:30 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 26 Aug 2020 10:42:30 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:57

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:13', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '29b7b93a-5528-4697-b43d-7a07cd05ecbd' | System | 26 Aug 2020 10:42:30 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 26 Aug 2020 10:42:30 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:16', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '29b7b93a-5528-4697-b43d-7a07cd05ecbd' | System | 26 Aug 2020 10:42:30 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 26 Aug 2020 10:42:30 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:22', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '29b7b93a-5528-4697-b43d-7a07cd05ecbd' | System | 26 Aug 2020 10:42:30 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 26 Aug 2020 10:42:30 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:35:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:25', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '29b7b93a-5528-4697-b43d-7a07cd05ecbd' | System | 26 Aug 2020 10:42:30 |
| User entered '26 Aug 2020 05:42'                                                                                                                                                                                                           | System | 26 Aug 2020 10:42:30 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 5' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:02', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'b709a0b5-92fa-4fbb-bf0c-165367d65481' | System | 27 Aug 2020 04:44:19 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 27 Aug 2020 04:44:19 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:57

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:05', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'b709a0b5-92fa-4fbb-bf0c-165367d65481' | System | 27 Aug 2020 04:44:19 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 27 Aug 2020 04:44:19 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:07', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'b709a0b5-92fa-4fbb-bf0c-165367d65481' | System | 27 Aug 2020 04:44:19 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 27 Aug 2020 04:44:19 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:10', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'b709a0b5-92fa-4fbb-bf0c-165367d65481' | System | 27 Aug 2020 04:44:19 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 27 Aug 2020 04:44:19 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:12', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'b709a0b5-92fa-4fbb-bf0c-165367d65481' | System | 27 Aug 2020 04:44:19 |
| User entered '26 Aug 2020 23:44'                                                                                                                                                                                                           | System | 27 Aug 2020 04:44:19 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 6' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:29', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'a2ba6c1b-ecfe-4b02-b3fa-c7123070e9d2' | System | 28 Aug 2020 08:35:42 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 28 Aug 2020 08:35:42 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:57

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:32', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'a2ba6c1b-ecfe-4b02-b3fa-c7123070e9d2' | System | 28 Aug 2020 08:35:42 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 28 Aug 2020 08:35:42 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:34', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'a2ba6c1b-ecfe-4b02-b3fa-c7123070e9d2' | System | 28 Aug 2020 08:35:42 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 28 Aug 2020 08:35:42 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:38', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'a2ba6c1b-ecfe-4b02-b3fa-c7123070e9d2' | System | 28 Aug 2020 08:35:42 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 28 Aug 2020 08:35:42 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:35:57

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:40', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'a2ba6c1b-ecfe-4b02-b3fa-c7123070e9d2' | System | 28 Aug 2020 08:35:42 |
| User entered '28 Aug 2020 03:35'                                                                                                                                                                                                           | System | 28 Aug 2020 08:35:42 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 7' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-29T00:23:51', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d39c997-7236-4cc7-8cb4-3c8ed32293b3' | System | 29 Aug 2020 05:24:05 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 29 Aug 2020 05:24:05 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:57

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:23:55', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d39c997-7236-4cc7-8cb4-3c8ed32293b3' | System | 29 Aug 2020 05:24:05 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 29 Aug 2020 05:24:05 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:23:57', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d39c997-7236-4cc7-8cb4-3c8ed32293b3' | System | 29 Aug 2020 05:24:05 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 29 Aug 2020 05:24:05 |

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-29T00:23:59', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d39c997-7236-4cc7-8cb4-3c8ed32293b3' | System | 29 Aug 2020 05:24:05 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 29 Aug 2020 05:24:05 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:02', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d39c997-7236-4cc7-8cb4-3c8ed32293b3' | System | 29 Aug 2020 05:24:05 |
| User entered '29 Aug 2020 00:24'                                                                                                                                                                                                           | System | 29 Aug 2020 05:24:05 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:05', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3b2d2b7c-b8c4-498d-93d9-f70650b6b6fa' | System | 22 Aug 2020 19:09:39 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 22 Aug 2020 19:09:39 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:10', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3b2d2b7c-b8c4-498d-93d9-f70650b6b6fa' | System | 22 Aug 2020 19:09:39 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 22 Aug 2020 19:09:39 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:13', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3b2d2b7c-b8c4-498d-93d9-f70650b6b6fa' | System | 22 Aug 2020 19:09:39 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 22 Aug 2020 19:09:39 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:17', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3b2d2b7c-b8c4-498d-93d9-f70650b6b6fa' | System | 22 Aug 2020 19:09:39 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 22 Aug 2020 19:09:39 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:20', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3b2d2b7c-b8c4-498d-93d9-f70650b6b6fa' | System | 22 Aug 2020 19:09:39 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 22 Aug 2020 19:09:39 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:24', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3b2d2b7c-b8c4-498d-93d9-f70650b6b6fa' | System | 22 Aug 2020 19:09:39 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 22 Aug 2020 19:09:39 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:31', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3b2d2b7c-b8c4-498d-93d9-f70650b6b6fa' | System | 22 Aug 2020 19:09:39 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 22 Aug 2020 19:09:39 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:34', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3b2d2b7c-b8c4-498d-93d9-f70650b6b6fa' | System | 22 Aug 2020 19:09:39 |
| User entered '22 Aug 2020 14:09'                                                                                                                                                                                                           | System | 22 Aug 2020 19:09:39 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:35:57

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 13:54' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 16:24' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 1, after vaccination (at home)' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:52', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '71c4d341-0787-4c3b-a948-52b85a938934' | System | 23 Aug 2020 02:19:24 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 02:19:24 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:54', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '71c4d341-0787-4c3b-a948-52b85a938934' | System | 23 Aug 2020 02:19:24 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 02:19:24 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:57', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '71c4d341-0787-4c3b-a948-52b85a938934' | System | 23 Aug 2020 02:19:24 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 02:19:24 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:19:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '71c4d341-0787-4c3b-a948-52b85a938934' | System | 23 Aug 2020 02:19:24 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 02:19:24 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:19:04', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '71c4d341-0787-4c3b-a948-52b85a938934' | System | 23 Aug 2020 02:19:24 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 02:19:24 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:19:06', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '71c4d341-0787-4c3b-a948-52b85a938934' | System | 23 Aug 2020 02:19:24 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 02:19:24 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-22T21:19:18', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '71c4d341-0787-4c3b-a948-52b85a938934' | System | 23 Aug 2020 02:19:24 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 23 Aug 2020 02:19:24 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:35:57

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:19:21', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '71c4d341-0787-4c3b-a948-52b85a938934' | System | 23 Aug 2020 02:19:24 |
| User entered '22 Aug 2020 21:19'                                                                                                                                                                                                           | System | 23 Aug 2020 02:19:24 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 17:19' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:57

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 2' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:57

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:21', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'fcd00f71-f2d7-4362-9ed0-0f5db61c3092' | System | 24 Aug 2020 02:14:18 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 24 Aug 2020 02:14:18 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:57

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:31', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'fcd00f71-f2d7-4362-9ed0-0f5db61c3092' | System | 24 Aug 2020 02:14:18 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 24 Aug 2020 02:14:18 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:57

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:34', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'fcd00f71-f2d7-4362-9ed0-0f5db61c3092' | System | 24 Aug 2020 02:14:18 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 24 Aug 2020 02:14:18 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:57

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:36', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'fcd00f71-f2d7-4362-9ed0-0f5db61c3092' | System | 24 Aug 2020 02:14:18 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 24 Aug 2020 02:14:18 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:57

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:38', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'fcd00f71-f2d7-4362-9ed0-0f5db61c3092' | System | 24 Aug 2020 02:14:18 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 24 Aug 2020 02:14:18 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:57

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:40', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'fcd00f71-f2d7-4362-9ed0-0f5db61c3092' | System | 24 Aug 2020 02:14:18 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 24 Aug 2020 02:14:18 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:51', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'fcd00f71-f2d7-4362-9ed0-0f5db61c3092' | System | 24 Aug 2020 02:14:18 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 24 Aug 2020 02:14:18 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:57

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:55', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'fcd00f71-f2d7-4362-9ed0-0f5db61c3092' | System | 24 Aug 2020 02:14:18 |
| User entered '23 Aug 2020 21:13'                                                                                                                                                                                                           | System | 24 Aug 2020 02:14:18 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:57

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:35:57

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 3' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:57

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:41:02', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3c25950c-2537-4601-b108-c272e4de02a4' | System | 25 Aug 2020 01:41:31 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 25 Aug 2020 01:41:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:57

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:41:06', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3c25950c-2537-4601-b108-c272e4de02a4' | System | 25 Aug 2020 01:41:31 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 25 Aug 2020 01:41:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:57

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:41:08', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3c25950c-2537-4601-b108-c272e4de02a4' | System | 25 Aug 2020 01:41:31 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 25 Aug 2020 01:41:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:57

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:41:11', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3c25950c-2537-4601-b108-c272e4de02a4' | System | 25 Aug 2020 01:41:31 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 25 Aug 2020 01:41:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:57

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:41:14', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3c25950c-2537-4601-b108-c272e4de02a4' | System | 25 Aug 2020 01:41:31 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 25 Aug 2020 01:41:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:57

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:41:17', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3c25950c-2537-4601-b108-c272e4de02a4' | System | 25 Aug 2020 01:41:31 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 25 Aug 2020 01:41:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-24T20:41:24', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3c25950c-2537-4601-b108-c272e4de02a4' | System | 25 Aug 2020 01:41:31 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 25 Aug 2020 01:41:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:35:57

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:41:27', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3c25950c-2537-4601-b108-c272e4de02a4' | System | 25 Aug 2020 01:41:31 |
| User entered '24 Aug 2020 20:41'                                                                                                                                                                                                           | System | 25 Aug 2020 01:41:31 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 4' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:57

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:34', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1caeb5f0-4911-4838-8727-da90ac242912' | System | 26 Aug 2020 10:42:57 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 26 Aug 2020 10:42:57 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:57

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:36', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1caeb5f0-4911-4838-8727-da90ac242912' | System | 26 Aug 2020 10:42:57 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 26 Aug 2020 10:42:57 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:57

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:39', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1caeb5f0-4911-4838-8727-da90ac242912' | System | 26 Aug 2020 10:42:57 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 26 Aug 2020 10:42:57 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:57

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:42', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1caeb5f0-4911-4838-8727-da90ac242912' | System | 26 Aug 2020 10:42:57 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 26 Aug 2020 10:42:57 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:57

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:46', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1caeb5f0-4911-4838-8727-da90ac242912' | System | 26 Aug 2020 10:42:57 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 26 Aug 2020 10:42:57 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:57

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:48', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1caeb5f0-4911-4838-8727-da90ac242912' | System | 26 Aug 2020 10:42:57 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 26 Aug 2020 10:42:57 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:52', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1caeb5f0-4911-4838-8727-da90ac242912' | System | 26 Aug 2020 10:42:57 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 26 Aug 2020 10:42:57 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:57

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:54', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1caeb5f0-4911-4838-8727-da90ac242912' | System | 26 Aug 2020 10:42:57 |
| User entered '26 Aug 2020 05:42'                                                                                                                                                                                                           | System | 26 Aug 2020 10:42:57 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:57

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:35:57

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 5' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:57

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:16', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'cfd16e47-ccb5-4813-bbc5-d4f95bfd5829' | System | 27 Aug 2020 04:44:39 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 27 Aug 2020 04:44:39 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:57

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:18', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'cfd16e47-ccb5-4813-bbc5-d4f95bfd5829' | System | 27 Aug 2020 04:44:39 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 27 Aug 2020 04:44:39 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:57

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:20', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'cfd16e47-ccb5-4813-bbc5-d4f95bfd5829' | System | 27 Aug 2020 04:44:39 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 27 Aug 2020 04:44:39 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:57

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:22', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'cfd16e47-ccb5-4813-bbc5-d4f95bfd5829' | System | 27 Aug 2020 04:44:39 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 27 Aug 2020 04:44:39 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:57

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:24', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'cfd16e47-ccb5-4813-bbc5-d4f95bfd5829' | System | 27 Aug 2020 04:44:39 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 27 Aug 2020 04:44:39 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:57

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:27', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'cfd16e47-ccb5-4813-bbc5-d4f95bfd5829' | System | 27 Aug 2020 04:44:39 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 27 Aug 2020 04:44:39 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:33', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'cfd16e47-ccb5-4813-bbc5-d4f95bfd5829' | System | 27 Aug 2020 04:44:39 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 27 Aug 2020 04:44:39 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:57

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:35', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'cfd16e47-ccb5-4813-bbc5-d4f95bfd5829' | System | 27 Aug 2020 04:44:39 |
| User entered '26 Aug 2020 23:44'                                                                                                                                                                                                           | System | 27 Aug 2020 04:44:39 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:57

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:35:57

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 6' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:57

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:46', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3f2b9ac5-e88c-4773-b059-cccfd8b1165c' | System | 28 Aug 2020 08:36:11 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 28 Aug 2020 08:36:11 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:57

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:48', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3f2b9ac5-e88c-4773-b059-cccfd8b1165c' | System | 28 Aug 2020 08:36:11 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 28 Aug 2020 08:36:11 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:57

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:51', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3f2b9ac5-e88c-4773-b059-cccfd8b1165c' | System | 28 Aug 2020 08:36:11 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 28 Aug 2020 08:36:11 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:57

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:53', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3f2b9ac5-e88c-4773-b059-cccfd8b1165c' | System | 28 Aug 2020 08:36:11 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 28 Aug 2020 08:36:11 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:57

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:54', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3f2b9ac5-e88c-4773-b059-cccfd8b1165c' | System | 28 Aug 2020 08:36:11 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 28 Aug 2020 08:36:11 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:57

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:57', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3f2b9ac5-e88c-4773-b059-cccfd8b1165c' | System | 28 Aug 2020 08:36:11 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 28 Aug 2020 08:36:11 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-28T03:36:03', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3f2b9ac5-e88c-4773-b059-cccfd8b1165c' | System | 28 Aug 2020 08:36:11 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 28 Aug 2020 08:36:11 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:57

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:36:09', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3f2b9ac5-e88c-4773-b059-cccfd8b1165c' | System | 28 Aug 2020 08:36:11 |
| User entered '28 Aug 2020 03:36'                                                                                                                                                                                                           | System | 28 Aug 2020 08:36:11 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:35:57

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 7' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:57

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:06', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aa384af4-14f2-4e6a-b803-1119db1f723a' | System | 29 Aug 2020 05:24:31 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 29 Aug 2020 05:24:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:57

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:10', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aa384af4-14f2-4e6a-b803-1119db1f723a' | System | 29 Aug 2020 05:24:31 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 29 Aug 2020 05:24:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:57

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:12', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aa384af4-14f2-4e6a-b803-1119db1f723a' | System | 29 Aug 2020 05:24:31 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 29 Aug 2020 05:24:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:57

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:15', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aa384af4-14f2-4e6a-b803-1119db1f723a' | System | 29 Aug 2020 05:24:31 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 29 Aug 2020 05:24:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:57

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:17', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aa384af4-14f2-4e6a-b803-1119db1f723a' | System | 29 Aug 2020 05:24:31 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 29 Aug 2020 05:24:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:57

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:19', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aa384af4-14f2-4e6a-b803-1119db1f723a' | System | 29 Aug 2020 05:24:31 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 29 Aug 2020 05:24:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:57

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 (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:24', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aa384af4-14f2-4e6a-b803-1119db1f723a' | System | 29 Aug 2020 05:24:31 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 29 Aug 2020 05:24:31 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:57

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:26', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aa384af4-14f2-4e6a-b803-1119db1f723a' | System | 29 Aug 2020 05:24:31 |
| User entered '29 Aug 2020 00:24'                                                                                                                                                                                                           | System | 29 Aug 2020 05:24:31 |

US3552140

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:35:57**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 12:00' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:35:57

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 11:59' | System | 22 Aug 2020 18:41:13 |

US3552140

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:57**

[Was Contact Attempted?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Mikayla Frye (b) (4)<br>(b) (4) | 29 Aug 2020 19:55:28 |

US3552140

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:57**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User entered '29 Aug 2020' | Mikayla Frye (b) (4)<br>(b) (4) | 29 Aug 2020 19:55:28 |

US3552140

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:57**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                            | Time (GMT)           |
|--------------------------------------------|---------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Mikayla Frye (b) (4)<br>(b) (4) | 29 Aug 2020 19:55:28 |

US3552140

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                            | Time (GMT)           |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Mikayla Frye (b) (4)<br>(b) (4) | 29 Aug 2020 19:55:28 |

US3552140

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

[Is the participant continuing to the next visit?](#)

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| User entered 'Yes (Y)' | Joan Siegner (b) (4) | 05 Sep 2020 18:21:57 |
|                        |                      |                      |
|                        |                      |                      |

US3552140

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:57**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Sep 2020 18:21:57 |

US3552140

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

[Was Contact Attempted?](#)

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| User entered 'Yes (Y)' | Joan Siegner (b) (4) | 05 Sep 2020 18:22:08 |
|                        |                      |                      |
|                        |                      |                      |

US3552140

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| User entered '05 Sep 2020' reason for change: Data Entry Error | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:32:56 |
| User entered '5 Sep 2020'                                      | Joan Siegner (b) (4)      | 05 Sep 2020 18:22:08 |
|                                                                |                           |                      |
|                                                                |                           |                      |

US3552140

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

[Please select one status for the follow-up contact](#)

| Audit                                      | User                 | Time (GMT)           |
|--------------------------------------------|----------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Joan Siegner (b) (4) | 05 Sep 2020 18:22:08 |
|                                            |                      |                      |
|                                            |                      |                      |

US3552140

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| User entered empty. | Joan Siegner (b) (4) | 05 Sep 2020 18:22:08 |
|                     |                      |                      |
|                     |                      |                      |

US3552140

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

[Is the participant continuing to the next visit?](#)

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| User entered 'Yes (Y)' | Joan Siegner (b) (4) | 14 Sep 2020 15:37:02 |
|                        |                      |                      |
|                        |                      |                      |

US3552140

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:57**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 14 Sep 2020 15:37:02 |

US3552140

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

[Was Contact Attempted?](#)

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| User entered 'Yes (Y)' | Joan Siegner (b) (4) | 14 Sep 2020 15:37:37 |
|                        |                      |                      |
|                        |                      |                      |

US3552140

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| User entered '12 Sep 2020' | Joan Siegner (b) (4) | 14 Sep 2020 15:37:37 |
|                            |                      |                      |
|                            |                      |                      |

US3552140

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

[Please select one status for the follow-up contact](#)

| Audit                                      | User                 | Time (GMT)           |
|--------------------------------------------|----------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Joan Siegner (b) (4) | 14 Sep 2020 15:37:37 |
|                                            |                      |                      |
|                                            |                      |                      |

US3552140

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| User entered empty. | Joan Siegner (b) (4) | 14 Sep 2020 15:37:37 |
|                     |                      |                      |
|                     |                      |                      |

US3552140

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

[Is the participant continuing to the next visit?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:21:28 |

US3552140

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:57**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Sep 2020 16:21:28 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:57

[Was this visit performed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:21:40 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:57

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '21 Sep 2020' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:21:40 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:57

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

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:21:40 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:57

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 21 Sep 2020 16:21:40 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

[Timepoint](#)

| Audit                                            | User                   | Time (GMT)           |
|--------------------------------------------------|------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Stanley Dublin (b) (4) | 21 Sep 2020 16:33:35 |
|                                                  | (b) (4)                |                      |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

[Were vital signs assessed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:33:35 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '21 Sep 2020' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:33:35 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                                        | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System).                    | System                 | 21 Sep 2020 16:33:45 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                        | 21 Sep 2020 16:33:45 |
| User entered '09:15' reason for change: Data Entry Error                                     | Stanley Dublin (b) (4) | 21 Sep 2020 16:33:45 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                 | 21 Sep 2020 16:33:35 |
| User entered empty.                                                                          | Stanley Dublin (b) (4) | 21 Sep 2020 16:33:35 |

US3552140

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 09:15' | System | 21 Sep 2020 16:33:45 |
| User entered empty.              | System | 21 Sep 2020 16:33:35 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

Temperature (xxx.x)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered '98.1' F | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:33:35 |

US3552140

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:35:57**

[Route of measurement](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (Oral)' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:33:35 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

[If Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:33:35 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

[Pulse \(xxx\)](#)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '100' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:33:35 |

US3552140

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:35:57**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 21 Sep 2020 16:33:35 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

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

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '14' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:33:35 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 21 Sep 2020 16:33:35 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

Systolic Blood Pressure (xxx)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '156' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:33:35 |

US3552140

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:35:57**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Sep 2020 16:33:35 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

Diastolic Blood Pressure (xxx)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '81' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:33:35 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:57

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Sep 2020 16:33:35 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

[Timepoint](#)

| Audit                                              | User                   | Time (GMT)           |
|----------------------------------------------------|------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Stanley Dublin (b) (4) | 21 Sep 2020 16:34:09 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

[Were vital signs assessed?](#)

| Audit                                                                                                                            | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System). | System                            | 21 Sep 2020 16:34:52 |
| User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System). | System                            | 21 Sep 2020 16:34:09 |
| User entered 'No (N)'                                                                                                            | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:34:09 |

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

Date of assessment (*dd MMM yyyy*)

| Audit                                                  | User                   | Time (GMT)           |
|--------------------------------------------------------|------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Stanley Dublin (b) (4) | 21 Sep 2020 16:34:24 |
| User entered '21 Sep 2020'                             | Stanley Dublin (b) (4) | 21 Sep 2020 16:34:09 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

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

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:34:09 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Sep 2020 16:34:09 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

Temperature (xxx.x)

| Audit                                                  | User                    | Time (GMT)           |
|--------------------------------------------------------|-------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Stanley Doublin (b) (4) | 21 Sep 2020 16:34:52 |
| User entered missing code ND - Not Done.               | Stanley Doublin (b) (4) | 21 Sep 2020 16:34:09 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

[Route of measurement](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:34:09 |

US3552140

**Folder:** Visit 2 Day 29 (1)

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

**Generated On:** 26 Nov 2020 09:35:57

[If Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:34:09 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

[Pulse \(xxx\)](#)

| Audit                                                  | User                   | Time (GMT)           |
|--------------------------------------------------------|------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Stanley Dublin (b) (4) | 21 Sep 2020 16:34:38 |
| User entered missing code ND - Not Done.               | Stanley Dublin (b) (4) | 21 Sep 2020 16:34:09 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Sep 2020 16:34:38 |
| User entered 'bpm'  | System | 21 Sep 2020 16:34:09 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                  | User                   | Time (GMT)           |
|--------------------------------------------------------|------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Stanley Dublin (b) (4) | 21 Sep 2020 16:34:38 |
| User entered missing code ND - Not Done.               | Stanley Dublin (b) (4) | 21 Sep 2020 16:34:09 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered empty.        | System | 21 Sep 2020 16:34:38 |
| User entered 'breaths/min' | System | 21 Sep 2020 16:34:09 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                  | User                   | Time (GMT)           |
|--------------------------------------------------------|------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Stanley Dublin (b) (4) | 21 Sep 2020 16:34:38 |
| User entered missing code ND - Not Done.               | Stanley Dublin (b) (4) | 21 Sep 2020 16:34:09 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Sep 2020 16:34:38 |
| User entered 'mmHg' | System | 21 Sep 2020 16:34:09 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                  | User                   | Time (GMT)           |
|--------------------------------------------------------|------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Stanley Dublin (b) (4) | 21 Sep 2020 16:34:38 |
| User entered missing code ND - Not Done.               | Stanley Dublin (b) (4) | 21 Sep 2020 16:34:09 |

US3552140

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 26 Nov 2020 09:35:57**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Sep 2020 16:34:38 |
| User entered 'mmHg' | System | 21 Sep 2020 16:34:09 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:57

[Was the physical examination performed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:35:06 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:57

Date of examination (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '21 Sep 2020' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:35:06 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

[Was study treatment given?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:36:33 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

[If No, reason not given](#)

| Audit                                                  | User                   | Time (GMT)           |
|--------------------------------------------------------|------------------------|----------------------|
| User entered 'Physician Decision (PHYSICIAN DECISION)' | Stanley Dublin (b) (4) | 21 Sep 2020 16:36:33 |

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

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

| Audit                                                                  | User                              | Time (GMT)           |
|------------------------------------------------------------------------|-----------------------------------|----------------------|
| User entered 'STILL RECOVERING FROM RECENT RETINAL DETACHMENT SURGERY' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:36:33 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

[What was the study treatment?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Sep 2020 16:36:33 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

What was the treatment date? (dd MMM yyyy)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:36:33 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

[What was the treatment time? \(00:00-23:59\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:36:33 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

[Treatment Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Sep 2020 16:36:33 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

[Which arm was used to give treatment?](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:36:33 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Sep 2020 16:36:33 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:57

[What was the route of administration for the study treatment?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Sep 2020 16:36:33 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:57

[Was the sample collected?](#)

| Audit                                                      | User                   | Time (GMT)           |
|------------------------------------------------------------|------------------------|----------------------|
| User entered 'Yes (Y)' reason for change: Data Entry Error | Stanley Dublin (b) (4) | 21 Sep 2020 16:37:17 |
| User entered 'No (N)'                                      | Stanley Dublin (b) (4) | 21 Sep 2020 16:36:41 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:57

Collection date (dd MMM yyyy)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| User entered '21 Sep 2020' reason for change: Data Entry Error | Stanley Dublin (b) (4) | 21 Sep 2020 16:37:17 |
| User entered empty.                                            | Stanley Dublin (b) (4) | 21 Sep 2020 16:36:41 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:57

Collection time (00:00-23:59)

| Audit                                                    | User                   | Time (GMT)           |
|----------------------------------------------------------|------------------------|----------------------|
| User entered '09:40' reason for change: Data Entry Error | Stanley Dublin (b) (4) | 21 Sep 2020 16:37:17 |
| User entered empty.                                      | Stanley Dublin (b) (4) | 21 Sep 2020 16:36:41 |

US3552140

**Folder:** Visit 2 Day 29 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 09:35:57

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 09:40' | System | 21 Sep 2020 16:37:17 |
| User entered empty.              | System | 21 Sep 2020 16:36:41 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:35:57

Collection date (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '21 Sep 2020' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:37:02 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:57

[Lab Test](#)

| Audit                                                        | User                   | Time (GMT)           |
|--------------------------------------------------------------|------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Stanley Dublin (b) (4) | 21 Sep 2020 16:37:02 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:57

[Was the sample collected?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:37:02 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:57

Collection time (00:00 - 23:59)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '09:45' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:37:02 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:57

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 09:45' | System | 21 Sep 2020 16:37:02 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:57

[Lab Test](#)

| Audit                                                        | User                   | Time (GMT)           |
|--------------------------------------------------------------|------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Stanley Dublin (b) (4) | 21 Sep 2020 16:37:02 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:57

[Was the sample collected?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:37:02 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:57

Collection time (00:00 - 23:59)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:37:02 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:57

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Sep 2020 16:37:02 |

US3552140

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

[Is the participant continuing to the next visit?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 29 Sep 2020 14:59:34 |

US3552140

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:57**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Sep 2020 14:59:34 |

US3552140

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:57**

[Was Contact Attempted?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 29 Sep 2020 14:59:49 |

US3552140

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:57**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '28 Sep 2020' | Stanley Dublin (b) (4)<br>(b) (4) | 29 Sep 2020 14:59:49 |

US3552140

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:57**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                              | Time (GMT)           |
|--------------------------------------------|-----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Stanley Dublin (b) (4)<br>(b) (4) | 29 Sep 2020 14:59:49 |

US3552140

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 29 Sep 2020 14:59:49 |

US3552140

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

[Is the participant continuing to the next visit?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 05 Oct 2020 18:08:55 |

US3552140

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:57**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Oct 2020 18:08:55 |

US3552140

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

[Was Contact Attempted?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 05 Oct 2020 18:09:04 |

US3552140

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:57**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| User entered '05 Oct 2020' reason for change: Data Entry Error | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:15 |
| User entered '5 Oct 2020'                                      | Stanley Dublin (b) (4)    | 05 Oct 2020 18:09:04 |

US3552140

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:57**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                   | Time (GMT)           |
|--------------------------------------------|------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Stanley Dublin (b) (4) | 05 Oct 2020 18:09:04 |

US3552140

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 05 Oct 2020 18:09:04 |

US3552140

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

[Is the participant continuing to the next visit?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 12 Oct 2020 19:49:58 |

US3552140

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:57**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Oct 2020 19:49:58 |

US3552140

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:57**

[Was Contact Attempted?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Stanley Dublin (b) (4)<br>(b) (4) | 12 Oct 2020 19:50:06 |

US3552140

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '12 Oct 2020' | Stanley Dublin (b) (4)<br>(b) (4) | 12 Oct 2020 19:50:06 |

US3552140

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:57**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                   | Time (GMT)           |
|--------------------------------------------|------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Stanley Dublin (b) (4) | 12 Oct 2020 19:50:06 |

US3552140

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Stanley Dublin (b) (4)<br>(b) (4) | 12 Oct 2020 19:50:06 |

US3552140

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:57**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:16:43 |

US3552140

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:57**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 16 Oct 2020 20:16:43 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:57

[Was this visit performed?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:16:53 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:57

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

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User entered '16 Oct 2020' | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:16:53 |

US3552140

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:16:53 |

US3552140

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:35:57**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 16 Oct 2020 20:16:53 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

[Were vital signs assessed?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6)                | 12 Nov 2020 14:41:53 |
| DataPoint Verified.    | (b) (4), (b) (6)                | 12 Nov 2020 14:41:13 |
| User entered 'No (N)'  | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:16:58 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

Date of assessment (*dd MMM yyyy*)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6)                | 12 Nov 2020 14:41:55 |
| DataPoint Verified.    | (b) (4), (b) (6)                | 12 Nov 2020 14:41:13 |
| User entered empty.    | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:16:58 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

[Time of assessment \(00:00-23:59\)](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6)                | 12 Nov 2020 14:41:56 |
| DataPoint Verified.    | (b) (4), (b) (6)                | 12 Nov 2020 14:41:13 |
| User entered empty.    | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:16:58 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Oct 2020 20:16:58 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

Temperature (xxx.x)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6)                | 12 Nov 2020 14:41:58 |
| DataPoint Verified.    | (b) (4), (b) (6)                | 12 Nov 2020 14:41:13 |
| User entered empty.    | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:16:58 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

[Route of measurement](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6)                | 12 Nov 2020 14:42:00 |
| DataPoint Verified.    | (b) (4), (b) (6)                | 12 Nov 2020 14:41:13 |
| User entered empty.    | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:16:58 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

[If Other, specify](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6)                | 12 Nov 2020 14:42:02 |
| DataPoint Verified.    | (b) (4), (b) (6)                | 12 Nov 2020 14:41:13 |
| User entered empty.    | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:16:58 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

[Pulse \(xxx\)](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6)                | 12 Nov 2020 14:42:04 |
| DataPoint Verified.    | (b) (4), (b) (6)                | 12 Nov 2020 14:41:13 |
| User entered empty.    | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:16:58 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Oct 2020 20:16:58 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

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

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6)                | 12 Nov 2020 14:42:06 |
| DataPoint Verified.    | (b) (4), (b) (6)                | 12 Nov 2020 14:41:13 |
| User entered empty.    | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:16:58 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

[Respiratory Rate units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Oct 2020 20:16:58 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

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

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6)                | 12 Nov 2020 14:42:08 |
| DataPoint Verified.    | (b) (4), (b) (6)                | 12 Nov 2020 14:41:13 |
| User entered empty.    | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:16:58 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Oct 2020 20:16:58 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

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

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6)                | 12 Nov 2020 14:42:10 |
| DataPoint Verified.    | (b) (4), (b) (6)                | 12 Nov 2020 14:41:13 |
| User entered empty.    | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:16:58 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:57

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Oct 2020 20:16:58 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:57

[Was the physical examination performed?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6)                | 12 Nov 2020 14:41:47 |
| DataPoint Verified.    | (b) (4), (b) (6)                | 12 Nov 2020 14:41:21 |
| User entered 'No (N)'  | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:17:04 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:57

Date of examination (dd MMM yyyy)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6)                | 12 Nov 2020 14:41:49 |
| DataPoint Verified.    | (b) (4), (b) (6)                | 12 Nov 2020 14:41:21 |
| User entered empty.    | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:17:04 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:57

[Was the sample collected?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6)                | 12 Nov 2020 14:41:38 |
| DataPoint Verified.    | (b) (4), (b) (6)                | 12 Nov 2020 14:41:26 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:17:15 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:57

Collection date (dd MMM yyyy)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| DataPoint Un-verified.     | (b) (4), (b) (6)                | 12 Nov 2020 14:41:40 |
| DataPoint Verified.        | (b) (4), (b) (6)                | 12 Nov 2020 14:41:26 |
| User entered '16 Oct 2020' | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:17:15 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:57

Collection time (00:00-23:59)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6)                | 12 Nov 2020 14:41:42 |
| DataPoint Verified.    | (b) (4), (b) (6)                | 12 Nov 2020 14:41:26 |
| User entered '14:20'   | Mikayla Frye (b) (4)<br>(b) (4) | 16 Oct 2020 20:17:15 |

US3552140

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:35:57**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Oct 2020 14:20' | System | 16 Oct 2020 20:17:15 |

US3552140

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:57

[Is the participant continuing to the next visit?](#)

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| User entered 'Yes (Y)' | Joan Siegner (b) (4) | 12 Nov 2020 15:54:33 |
|                        |                      |                      |
|                        |                      |                      |

US3552140

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:35:57**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Nov 2020 15:54:33 |

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 71' | System | 22 Aug 2020 18:41:13 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[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 (e1d2cd685b0a0b02)', Time: '2020-10-29T07:15:03', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'bcd59382-3ce9-498d-9b35-2e45688bff04' | System | 29 Oct 2020 12:16:21 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 29 Oct 2020 12:16:21 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

Have you been exposed to someone with 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 (e1d2cd685b0a0b02)', Time: '2020-10-29T07:15:21', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'bcd59382-3ce9-498d-9b35-2e45688bff04' | System | 29 Oct 2020 12:16:21 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 29 Oct 2020 12:16:21 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-10-29T07:16:12', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'bcd59382-3ce9-498d-9b35-2e45688bff04' | System | 29 Oct 2020 12:16:21 |
| User entered '29 Oct 2020 07:16:12'                                                                                                                                                                                                        | System | 29 Oct 2020 12:16:21 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 22 Aug 2020 18:41:13 |
| User entered '29 Oct 2020 00:01' | System | 22 Aug 2020 18:41:13 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 22 Aug 2020 18:41:13 |
| User entered '02 Nov 2020 23:59' | System | 22 Aug 2020 18:41:13 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 78' | System | 22 Aug 2020 18:41:13 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[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 (e1d2cd685b0a0b02)', Time: '2020-11-05T06:30:06', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'f0a8f21e-6578-4e3d-aa54-f1a40bba2829' | System | 05 Nov 2020 12:31:09 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 05 Nov 2020 12:31:09 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

Have you been exposed to someone with 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 (e1d2cd685b0a0b02)', Time: '2020-11-05T06:31:01', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'f0a8f21e-6578-4e3d-aa54-f1a40bba2829' | System | 05 Nov 2020 12:31:09 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 05 Nov 2020 12:31:09 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-11-05T06:31:08', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'f0a8f21e-6578-4e3d-aa54-f1a40bba2829' | System | 05 Nov 2020 12:31:09 |
| User entered '05 Nov 2020 06:31:08'                                                                                                                                                                                                        | System | 05 Nov 2020 12:31:09 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 22 Aug 2020 18:41:13 |
| User entered '05 Nov 2020 00:01' | System | 22 Aug 2020 18:41:13 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 22 Aug 2020 18:41:13 |
| User entered '09 Nov 2020 23:59' | System | 22 Aug 2020 18:41:13 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 22 Aug 2020 18:41:13 |
| User entered 'Day 92' | System | 22 Aug 2020 18:41:13 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

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 (e1d2cd685b0a0b02)', Time: '2020-11-19T07:16:02', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5d46b94a-46e7-4268-8006-8b9f19f0c2cc' | System | 19 Nov 2020 13:16:42 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 19 Nov 2020 13:16:42 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Have you been exposed to someone with 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 (e1d2cd685b0a0b02)', Time: '2020-11-19T07:16:15', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5d46b94a-46e7-4268-8006-8b9f19f0c2cc' | System | 19 Nov 2020 13:16:42 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 19 Nov 2020 13:16:42 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-11-19T07:16:39', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5d46b94a-46e7-4268-8006-8b9f19f0c2cc' | System | 19 Nov 2020 13:16:42 |
| User entered '19 Nov 2020 07:16:39'                                                                                                                                                                                                        | System | 19 Nov 2020 13:16:42 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 22 Aug 2020 18:41:13 |
| User entered '19 Nov 2020 00:01' | System | 22 Aug 2020 18:41:13 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 22 Aug 2020 18:41:13 |
| User entered '23 Nov 2020 23:59' | System | 22 Aug 2020 18:41:13 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 61' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '19 Oct 2020 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '23 Oct 2020 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 68' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '26 Oct 2020 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '30 Oct 2020 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 75' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '02 Nov 2020 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '06 Nov 2020 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '09 Nov 2020 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '13 Nov 2020 23:59' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '16 Nov 2020 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '20 Nov 2020 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '23 Nov 2020 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '27 Nov 2020 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '30 Nov 2020 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '04 Dec 2020 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '07 Dec 2020 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '11 Dec 2020 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '14 Dec 2020 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '18 Dec 2020 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '21 Dec 2020 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '25 Dec 2020 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '28 Dec 2020 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '01 Jan 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '04 Jan 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '08 Jan 2021 23:59' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '11 Jan 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '15 Jan 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '18 Jan 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '22 Jan 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '25 Jan 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '29 Jan 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '01 Feb 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '05 Feb 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '08 Feb 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '12 Feb 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '15 Feb 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '19 Feb 2021 23:59' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '22 Feb 2021 00:01' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '26 Feb 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '01 Mar 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '05 Mar 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '08 Mar 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '12 Mar 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '15 Mar 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '19 Mar 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '22 Mar 2021 00:01' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '26 Mar 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '29 Mar 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '02 Apr 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '05 Apr 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '09 Apr 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '12 Apr 2021 00:01' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '16 Apr 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '19 Apr 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '23 Apr 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '26 Apr 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '30 Apr 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '03 May 2021 00:01' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '07 May 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '10 May 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '14 May 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '17 May 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '21 May 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '24 May 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '28 May 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '31 May 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '04 Jun 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '07 Jun 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '11 Jun 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '14 Jun 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '18 Jun 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '21 Jun 2021 00:01' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '25 Jun 2021 23:59' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '28 Jun 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '02 Jul 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '05 Jul 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '09 Jul 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '12 Jul 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '16 Jul 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '19 Jul 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '23 Jul 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '26 Jul 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '30 Jul 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '02 Aug 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '06 Aug 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '09 Aug 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '13 Aug 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '16 Aug 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '20 Aug 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '23 Aug 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '27 Aug 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '30 Aug 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '03 Sep 2021 23:59' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '06 Sep 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '10 Sep 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '13 Sep 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '17 Sep 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '20 Sep 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '24 Sep 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '27 Sep 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '01 Oct 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '04 Oct 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '08 Oct 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '11 Oct 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '15 Oct 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '18 Oct 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '22 Oct 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '25 Oct 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '29 Oct 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '01 Nov 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '05 Nov 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '08 Nov 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '12 Nov 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '15 Nov 2021 00:01' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '19 Nov 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '22 Nov 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '26 Nov 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '29 Nov 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '03 Dec 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '06 Dec 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '10 Dec 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '13 Dec 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '17 Dec 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '20 Dec 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '24 Dec 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '27 Dec 2021 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '31 Dec 2021 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '03 Jan 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '07 Jan 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '10 Jan 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '14 Jan 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '17 Jan 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '21 Jan 2022 23:59' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '24 Jan 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '28 Jan 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '31 Jan 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '04 Feb 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '07 Feb 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '11 Feb 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '14 Feb 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '18 Feb 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '21 Feb 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '25 Feb 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '28 Feb 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '04 Mar 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '07 Mar 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '11 Mar 2022 23:59' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '14 Mar 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '18 Mar 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '21 Mar 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '25 Mar 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '28 Mar 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '01 Apr 2022 23:59' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '04 Apr 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '08 Apr 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '11 Apr 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '15 Apr 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '18 Apr 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '22 Apr 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '25 Apr 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '29 Apr 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '02 May 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '06 May 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '09 May 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '13 May 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '16 May 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '20 May 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '23 May 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '27 May 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '30 May 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '03 Jun 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '06 Jun 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '10 Jun 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '13 Jun 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '17 Jun 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '20 Jun 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '24 Jun 2022 23:59' | System | 20 Nov 2020 01:21:14 |

**US3552140**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '27 Jun 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '01 Jul 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '04 Jul 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '08 Jul 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '11 Jul 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '15 Jul 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '18 Jul 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '22 Jul 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '25 Jul 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '29 Jul 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '01 Aug 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '05 Aug 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '08 Aug 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '12 Aug 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 01:21:14 |

US3552140

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '15 Aug 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '19 Aug 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '22 Aug 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '26 Aug 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '29 Aug 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '02 Sep 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '05 Sep 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '09 Sep 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '12 Sep 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '16 Sep 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '19 Sep 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '23 Sep 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '26 Sep 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '30 Sep 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '03 Oct 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '07 Oct 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 01:21:14 |

**US3552140**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '10 Oct 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '14 Oct 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '17 Oct 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '21 Oct 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:57

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '24 Oct 2022 00:01' | System | 20 Nov 2020 01:21:14 |

US3552140

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:35:57**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 01:21:14 |
| Amendment Manager: User entered '28 Oct 2022 23:59' | System | 20 Nov 2020 01:21:14 |

US3552140

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

[Was Contact Attempted?](#)

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| User entered 'Yes (Y)' | Joan Siegner (b) (4) | 12 Nov 2020 15:54:46 |
|                        |                      |                      |
|                        |                      |                      |

US3552140

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| User entered '18 Nov 2020' reason for change: Data Entry Error | Cassandra Zehenny (b) (4) | 19 Nov 2020 15:10:36 |
| User entered '12 Nov 2020'                                     | Joan Siegner (b) (4)      | 12 Nov 2020 15:54:46 |
|                                                                |                           |                      |
|                                                                |                           |                      |

US3552140

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:35:57**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                 | Time (GMT)           |
|--------------------------------------------|----------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Joan Siegner (b) (4) | 12 Nov 2020 15:54:46 |
|                                            |                      |                      |
|                                            |                      |                      |

US3552140

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:57

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| User entered empty. | Joan Siegner (b) (4) | 12 Nov 2020 15:54:46 |
|                     |                      |                      |
|                     |                      |                      |

US3552140

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:35:57

[Did the participant experience any adverse events?](#)

| Audit                                                                                              | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                | (b) (4), (b) (6)      | 30 Oct 2020 15:47:32 |
| User closed query 'Please change response to "yes" - SAE is reported . ' (Site from CRA).          | (b) (4), (b) (6)      | 23 Sep 2020 13:59:16 |
| Query 'Please change response to "yes" - SAE is reported . ' answered with 'done' (Site from CRA). | Joan Siegner (b) (4)  | 19 Sep 2020 12:02:33 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                                         | Joan Siegner (b) (4)  | 19 Sep 2020 12:02:25 |
| User opened query 'Please change response to "yes" - SAE is reported . ' (Site from CRA).          | (b) (4), (b) (6)      | 16 Sep 2020 18:50:04 |
| User entered 'No (N)' reason for change: Data Entry Error                                          | Heather Douds (b) (4) | 10 Sep 2020 15:10:59 |
| User entered 'Yes (Y)'                                                                             | Joan Siegner (b) (4)  | 05 Sep 2020 19:56:30 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 14 Oct 2020 20:33:05 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 11 Sep 2020 13:54:36 |
| User entered<br>'USA-US089-2020-mRNA-1273-P301000002' | System           | 11 Sep 2020 13:53:03 |
| User entered 'New'                                    | (b) (4), (b) (6) | 11 Sep 2020 13:53:03 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Adverse event](#)

| Audit                                                                                                                                                                                                                                        | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                          | (b) (4), (b) (6)      | 14 Oct 2020 20:33:07 |
| User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Retinal detachment, LLT: Retinal detachment - version MedDRA\\23.0. | Coder Import (b) (4)  | 16 Sep 2020 11:27:35 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                                                      | (b) (4)               | 16 Sep 2020 11:27:35 |
| Data point term sent to Coder                                                                                                                                                                                                                | System                | 12 Sep 2020 15:22:58 |
| User entered 'Retinal detachment of left eye' reason for change: New Information                                                                                                                                                             | Heather Douds (b) (4) | 12 Sep 2020 15:22:34 |
| Data point term sent to Coder                                                                                                                                                                                                                | System                | 10 Sep 2020 15:37:28 |
| User entered 'Vision changes'                                                                                                                                                                                                                | Heather Douds (b) (4) | 10 Sep 2020 15:36:52 |
|                                                                                                                                                                                                                                              | (b) (4)               |                      |

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**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:35:57

[Was this a medically-attended AE?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:08 |
| User entered 'Yes (Y)' | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:10 |
| User entered 'No (N)' | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                                                                                  | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)      | 14 Oct 2020 20:33:11 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                | 10 Sep 2020 15:37:08 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 10 Sep 2020 15:37:08 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Heather Douds (b) (4) | 10 Sep 2020 15:37:08 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                | 10 Sep 2020 15:36:52 |
| User entered empty.                                                                    | Heather Douds (b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

Start date (dd MMM yyyy)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 11 Nov 2020 14:45:46 |
| DataPoint Un-verified.                                         | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:38 |
| User entered '08 Sep 2020' reason for change: Data Entry Error | (b) (4)                   |                      |
|                                                                | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:38 |
| DataPoint Verified.                                            | (b) (4)                   |                      |
|                                                                | (b) (4), (b) (6)          | 14 Oct 2020 20:33:15 |
| User entered '8 Sep 2020'                                      | Heather Douds (b) (4)     | 10 Sep 2020 15:36:52 |
|                                                                | (b) (4)                   |                      |

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Start time \(00:00-23:59\)](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:16 |
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 10 Sep 2020 15:36:52 |

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Ongoing?](#)

| Audit                                                    | User                             | Time (GMT)           |
|----------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:18 |
| User entered 'No (N)' reason for change: New Information | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:19:01 |
| User entered 'Yes (Y)'                                   | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                                                                                                                                  | User                  | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                    | (b) (4), (b) (6)      | 14 Oct 2020 20:33:20 |
| User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).             | System                | 17 Sep 2020 20:19:01 |
| Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System). | System                | 17 Sep 2020 20:19:01 |
| User entered '12 Sep 2020' reason for change: New Information                                                                                                          | Heather Douds (b) (4) | 17 Sep 2020 20:19:01 |
| User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).             | System                | 17 Sep 2020 20:18:38 |
| User entered empty.                                                                                                                                                    | Heather Douds (b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

End time (00:00-23:59)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:21 |
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[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) | 18 Sep 2020 15:41:06 |
| 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) | 16 Sep 2020 18:39:27 |
| User entered empty.                                                                                                                                                                                         | System           | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Severity](#)

| Audit                                          | User                             | Time (GMT)           |
|------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:23 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Is the adverse event serious?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:25 |
| User entered 'Yes (Y)' | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Death](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:27 |
| User entered '0'    | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Life threatening](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:29 |
| User entered '0'    | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

US3552140

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:35:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:30 |
| User entered '0'    | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:32 |
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

Hospital Discharge Date (dd MMM yyyy)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:34 |
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Admitted to ICU?](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:35 |
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Number of Days in ICU](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:37 |
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Persistent or significant disability or incapacity](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:38 |
| User entered '0'    | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Congenital anomaly or birth defect](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:39 |
| User entered '0'    | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Other medically important event](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:41 |
| User entered '1'    | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Relationship to investigational product](#)

| Audit                                                                                                                                            | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                              | (b) (4), (b) (6)      | 14 Oct 2020 20:33:43 |
| User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).          | (b) (4), (b) (6)      | 18 Sep 2020 15:40:33 |
| Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'done' (Site from Safety). | Heather Douds (b) (4) | 17 Sep 2020 20:19:11 |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                       | System                | 17 Sep 2020 20:18:38 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).                                                           | System                | 17 Sep 2020 20:18:38 |
| User entered 'Not Related (NOT RELATED)' reason for change: New Information                                                                      | Heather Douds (b) (4) | 17 Sep 2020 20:18:38 |
| User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).          | (b) (4), (b) (6)      | 11 Sep 2020 13:48:19 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                       | System                | 10 Sep 2020 15:36:52 |
| User entered empty.                                                                                                                              | Heather Douds (b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Relationship to Study Procedure](#)

| Audit                                                                                  | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)      | 14 Oct 2020 20:33:45 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                | 17 Sep 2020 20:18:38 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 17 Sep 2020 20:18:38 |
| User entered 'Not Related (NOT RELATED)' reason for change: New Information            | Heather Douds (b) (4) | 17 Sep 2020 20:18:38 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                | 10 Sep 2020 15:36:52 |
| User entered empty.                                                                    | Heather Douds (b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

Action taken with investigational product

| Audit                                                                                                                                                                                                                                                                                      | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)      | 04 Nov 2020 15:56:05 |
| User closed query 'Per CDM: Reason for Dosing discontinuation is AE on the Dosing discontinuation form, however the Action with Investigational product is not Investigational product withdrawn. Please reconcile and update data accordingly, else clarify.' (Site from DM).             | (b) (4), (b) (6)      | 30 Oct 2020 05:40:19 |
| Query 'Per CDM: Reason for Dosing discontinuation is AE on the Dosing discontinuation form, however the Action with Investigational product is not Investigational product withdrawn. Please reconcile and update data accordingly, else clarify.' answered with 'updated' (Site from DM). | Heather Douds (b) (4) | 29 Oct 2020 15:23:16 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                     | Heather Douds (b) (4) | 29 Oct 2020 15:23:04 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution                                                                                                                                                                                       | Heather Douds (b) (4) | 29 Oct 2020 15:23:04 |
| User opened query 'Per CDM: Reason for Dosing discontinuation is AE on the Dosing discontinuation form, however the Action with Investigational product is not Investigational product withdrawn. Please reconcile and update data accordingly, else clarify.' (Site from DM).             | (b) (4), (b) (6)      | 29 Oct 2020 09:30:00 |
| DataPoint Verified.                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)      | 14 Oct 2020 20:33:47 |
| User closed query 'PV Query: Please provide action taken with study drug, along with dechallenge and rechallenge for event of retinal detachment of left eye.' (Site from Safety).                                                                                                         | (b) (4), (b) (6)      | 18 Sep 2020 15:40:37 |
| Query 'PV Query: Please provide action taken with study drug, along with dechallenge and rechallenge for event of retinal detachment of left eye.' answered with 'done' (Site from Safety).                                                                                                | Heather Douds (b) (4) | 17 Sep 2020 20:19:15 |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                                                                                                 | System                | 17 Sep 2020 20:18:38 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).                                                                                                                                                                                                     | System                | 17 Sep 2020 20:18:38 |
| User entered 'None (NONE)' reason for change: New Information                                                                                                                                                                                                                              | Heather Douds (b) (4) | 17 Sep 2020 20:18:38 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Action taken with investigational product](#)

| Audit                                                                                                                                                                              | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User opened query 'PV Query: Please provide action taken with study drug, along with dechallenge and rechallenge for event of retinal detachment of left eye.' (Site from Safety). | (b) (4), (b) (6)                 | 16 Sep 2020 18:39:43 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                         | System                           | 10 Sep 2020 15:36:52 |
| User entered empty.                                                                                                                                                                | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[None](#)

| Audit                                                                                                                              | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:49 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System                           | 12 Sep 2020 15:22:34 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System                           | 10 Sep 2020 15:36:52 |
| User entered '0'                                                                                                                   | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Concomitant Medication](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | User                                                 | Time (GMT)                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|----------------------------------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)                                     | 14 Oct 2020 20:33:51                         |
| User closed query 'PV Query: It was reported that the subject started three new medications. Please provide the medications and any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).<br>Query 'PV Query: It was reported that the subject started three new medications. Please provide the medications and any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'added to con meds' (Site from Safety).<br>User entered '1' reason for change: New Information | (b) (4), (b) (6)<br>Heather Douds (b) (4)            | 18 Sep 2020 15:40:41<br>17 Sep 2020 20:19:26 |
| User entered '1' reason for change: New Information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Heather Douds (b) (4)                                | 17 Sep 2020 20:18:38                         |
| User opened query 'PV Query: It was reported that the subject started three new medications. Please provide the medications and any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).<br>User entered '0'                                                                                                                                                                                                                                                                                                                                                                             | (b) (4)<br>(b) (4), (b) (6)<br>Heather Douds (b) (4) | 16 Sep 2020 18:40:18<br>10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Concomitant Procedure](#)

| Audit                                                                                                                                             | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                               | (b) (4), (b) (6)      | 14 Oct 2020 20:33:52 |
| User closed query 'PV Query: Noted the subject had surgical correction - please specify what surgery was performed.' (Site from Safety).          | (b) (4), (b) (6)      | 18 Sep 2020 15:40:48 |
| Query 'PV Query: Noted the subject had surgical correction - please specify what surgery was performed.' answered with 'done' (Site from Safety). | Heather Douds (b) (4) | 17 Sep 2020 20:20:28 |
| User opened query 'PV Query: Noted the subject had surgical correction - please specify what surgery was performed.' (Site from Safety).          | (b) (4), (b) (6)      | 16 Sep 2020 18:40:01 |
| User entered '1' reason for change: New Information                                                                                               | Heather Douds (b) (4) | 12 Sep 2020 15:22:34 |
| User entered '0'                                                                                                                                  | Heather Douds (b) (4) | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Outcome](#)

| Audit                                                                                                                                                                                                                                             | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                               | (b) (4), (b) (6)      | 14 Oct 2020 20:33:56 |
| 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)      | 18 Sep 2020 15:40:55 |
| 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 'done' (Site from Safety). | Heather Douds (b) (4) | 17 Sep 2020 20:20:34 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error                                                                                                                                                        | Heather Douds (b) (4) | 17 Sep 2020 20:18:38 |
| 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)      | 16 Sep 2020 18:39:13 |
| User entered 'Unknown (UNKNOWN)'                                                                                                                                                                                                                  | Heather Douds (b) (4) | 10 Sep 2020 15:36:52 |

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 20:33:58 |
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 10 Sep 2020 15:36:52 |

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                               | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                 | (b) (4), (b) (6)      | 14 Oct 2020 20:34:00 |
| User closed query 'PV Query: Please provide any relevant diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).                                                                                                                                                     | (b) (4), (b) (6)      | 18 Sep 2020 15:41:50 |
| User closed query 'PV Query: Please confirm the start date of the reported medical history "hypertension" and consider removing the duplicate entry.' (Site from Safety).                                                                                                                                           | (b) (4), (b) (6)      | 18 Sep 2020 15:41:46 |
| User closed query 'PV Query: Please provide ophthalmologist report 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.if available.' (Site from Safety).          | (b) (4), (b) (6)      | 18 Sep 2020 15:41:43 |
| User closed query 'PV Query: Please report if the subject had any risk factors (i.e glaucoma, family history, myopia, cataract removal, eye injury, etc)' (Site from Safety).                                                                                                                                       | (b) (4), (b) (6)      | 18 Sep 2020 15:41:31 |
| User closed query 'PV Query: This patient saw an OPH for the treatment of the retinal detachment. What was the suspected cause of the retinal detachment?' (Site from Safety).                                                                                                                                      | (b) (4), (b) (6)      | 18 Sep 2020 15:41:25 |
| Query 'PV Query: Please provide ophthalmologist report 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.if available.' answered with 'done' (Site from Safety). | Heather Douds (b) (4) | 17 Sep 2020 20:48:59 |
| Query 'PV Query: This patient saw an OPH for the treatment of the retinal detachment. What was the suspected cause of the retinal detachment?' answered with 'no suspected cause listed in medical records' (Site from Safety).                                                                                     | Heather Douds (b) (4) | 17 Sep 2020 20:27:22 |
| Query 'PV Query: Please report if the subject had any risk factors (i.e glaucoma, family history, myopia, cataract removal, eye injury, etc)' answered with 'history of autoimmune disease, unknown family history' (Site from Safety).                                                                             | Heather Douds (b) (4) | 17 Sep 2020 20:27:06 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | User                             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User entered 'CONTACTED SUBJECT VIA PHONE AT 9:49 ON 9/10/2020 TO FOLLOW UP ON NEW MEDICATION; SUBJECT SHARED THAT SHE WAS CURRENTLY EXPERIENCING NEW VISION CHANGES/PARTIAL VISION LOSS IN HER LEFT EYE. SHE HAD ALREADY CONTACTED HER OPHTHALMOLOGIST AND WAS WAITING FOR A RETURN CALL. SEEN BY OPHTHALMOLOGIST 9/10, DIAGNOSED WITH RETINAL DETACHMENT OF LEFT EYE, SURGICALLY CORRECTED ON 9/11. THREE NEW MEDICATIONS STARTED, WILL UPDATE CON MEDS WHEN NAMES ARE AVAILABLE. RECORDS NOT YET AVAILABLE TO SITE, WILL SEND WHEN WE HAVE RECEIVED THEM.<br /><br />Will fax this afternoon, no lab tests performed. Subject has history of autoimmune disease, unknown if there is family history. No suspected cause listed in medical records.' reason for change: New Information | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:25:07 |
| Query 'PV Query: Please provide any relevant diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no lab tests' (Site from Safety).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:22:18 |
| Query 'PV Query: Please confirm the start date of the reported medical history "hypertension" and consider removing the duplicate entry.' answered with 'done' (Site from Safety).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:20:41 |
| User opened query 'PV Query: This patient saw an OPH for the treatment of the retinal detachment. What was the suspected cause of the retinal detachment?' (Site from Safety).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | (b) (4), (b) (6)                 | 16 Sep 2020 20:01:00 |
| User opened query 'PV Query: Please report if the subject had any risk factors (i.e glaucoma, family history, myopia, cataract removal, eye injury, etc)' (Site from Safety).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)                 | 16 Sep 2020 18:41:22 |
| User opened query 'PV Query: Please provide any relevant diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | (b) (4), (b) (6)                 | 16 Sep 2020 18:41:02 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:57

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| User opened query 'PV Query: Please provide ophthalmologist report 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.if available.' (Site from Safety).                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)      | 16 Sep 2020 18:40:48 |
| User opened query 'PV Query: Please confirm the start date of the reported medical history "hypertension" and consider removing the duplicate entry.' (Site from Safety).                                                                                                                                                                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)      | 16 Sep 2020 18:40:38 |
| User entered 'CONTACTED SUBJECT VIA PHONE AT 9:49 ON 9/10/2020 TO FOLLOW UP ON NEW MEDICATION; SUBJECT SHARED THAT SHE WAS CURRENTLY EXPERIENCING NEW VISION CHANGES/PARTIAL VISION LOSS IN HER LEFT EYE. SHE HAD ALREADY CONTACTED HER OPHTHALMOLOGIST AND WAS WAITING FOR A RETURN CALL. Seen by ophthalmologist 9/10, diagnosed with retinal detachment of left eye, surgically corrected on 9/11. Three new medications started, will update con meds when names are available. Records not yet available to site, will send when we have received them.' reason for change: New Information | Heather Douds (b) (4) | 12 Sep 2020 15:22:34 |
| User entered 'CONTACTED SUBJECT VIA PHONE AT 9:49 on 9/10/2020 TO FOLLOW UP ON NEW MEDICATION; SUBJECT SHARED THAT SHE WAS CURRENTLY EXPERIENCING NEW VISION CHANGES/PARTIAL VISION LOSS IN HER LEFT EYE. SHE HAD ALREADY CONTACTED HER OPHTHALMOLOGIST AND WAS WAITING FOR A RETURN CALL. WILL FOLLOW UP WITH SUBJECT AND GET RECORDS.' reason for change: Data Entry Error                                                                                                                                                                                                                     | Heather Douds (b) (4) | 10 Sep 2020 15:38:16 |
| User entered 'Contacted subject via phone at 9:49 this AM to follow up on new medication; subject shared that she was currently experiencing new vision changes/partial vision loss in her left eye. She had already contacted her ophthalmologist and was waiting for a return call. Will follow up with subject and get records.'                                                                                                                                                                                                                                                              | Heather Douds (b) (4) | 10 Sep 2020 15:36:52 |

v6.020 DTW (1102)

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**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:35:57

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 10 Sep 2020 15:36:52 |

US3552140

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:35:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 10 Sep 2020 15:36:52 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 28 Oct 2020 15:27:42 |
| Un-reviewed for Safety.                               | (b) (4), (b) (6) | 19 Oct 2020 15:28:55 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 05 Oct 2020 12:57:03 |
| User entered<br>'USA-US089-2020-mRNA-1273-P301000007' | System           | 05 Oct 2020 12:56:51 |
| User entered 'New'                                    | (b) (4), (b) (6) | 05 Oct 2020 12:56:51 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Adverse event](#)

| Audit                                                                                                                                                                                                                                                                                     | User                                 | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)                     | 28 Oct 2020 15:27:42 |
| User closed query 'PV Query: It was reported the tears were on bilateral retinas. Please confirm if the horseshoe tear occurred in both eyes? Please consider updating the event term, if applicable' (Site from Safety).                                                                 | (b) (4), (b) (6)                     | 27 Oct 2020 19:25:35 |
| Query 'PV Query: It was reported the tears were on bilateral retinas. Please confirm if the horseshoe tear occurred in both eyes? Please consider updating the event term, if applicable' answered with 'Horseshoe tear of right eye. retinal detachment of left eye' (Site from Safety). | (b) (4), (b) (6)                     | 26 Oct 2020 16:51:41 |
| User opened query 'PV Query: It was reported the tears were on bilateral retinas. Please confirm if the horseshoe tear occurred in both eyes? Please consider updating the event term, if applicable' (Site from Safety).                                                                 | (b) (4), (b) (6)                     | 22 Oct 2020 16:28:00 |
| User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Retinal tear, LLT: Retinal tear - version MedDRA\23.0.                                                           | Coder Import (b) (4)<br>(b) (4)      | 03 Oct 2020 07:08:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                                                                                                                    | Coder Import (b) (4)<br>(b) (4)      | 03 Oct 2020 07:08:46 |
| Data point term sent to Coder                                                                                                                                                                                                                                                             | System                               | 02 Oct 2020 19:16:59 |
| User entered 'Horseshoe tear of right eye'                                                                                                                                                                                                                                                | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Was this a medically-attended AE?](#)

| Audit                  | User                                 | Time (GMT)           |
|------------------------|--------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                     | 28 Oct 2020 15:27:42 |
| User entered 'Yes (Y)' | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                                 | Time (GMT)           |
|-----------------------|--------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                     | 28 Oct 2020 15:27:42 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                                 | Time (GMT)           |
|-----------------------|--------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                     | 28 Oct 2020 15:27:42 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                    | User                      | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6)          | 11 Nov 2020 14:46:02 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                   | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:55 |
| User entered '01 Oct 2020' reason for change: Data Entry Error                                                                                                                                                                                                                           | (b) (4)                   |                      |
|                                                                                                                                                                                                                                                                                          | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:55 |
| DataPoint Verified.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User closed query 'Please verify start and end dates. Procedures related to this condition were done on 06Oct and 09Oct .' (Site from CRA).                                                                                                                                              | (b) (4), (b) (6)          | 18 Oct 2020 02:16:25 |
| Query 'Please verify start and end dates. Procedures related to this condition were done on 06Oct and 09Oct .' answered with 'Procedures were done 01Oct and 06Oct. 09Oct was a follow up appointment with her eye doctor- no procedures done on this date. Thank you.' (Site from CRA). | Cassandra Zehenny (b) (4) | 15 Oct 2020 15:22:27 |
| User opened query 'Please verify start and end dates. Procedures related to this condition were done on 06Oct and 09Oct .' (Site from CRA).                                                                                                                                              | (b) (4), (b) (6)          | 14 Oct 2020 21:00:52 |
| User entered '1 Oct 2020'                                                                                                                                                                                                                                                                | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

Start time (00:00-23:59)

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User entered empty. | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |
|                     | (b) (4)                   |                      |

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**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:35:57

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

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[Ongoing?](#)

| Audit                 | User                      | Time (GMT)           |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                                                                                                                                  | User                      | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                    | (b) (4), (b) (6)          | 28 Oct 2020 15:50:28 |
| User closed query 'Please consider updating end date, procedure date for condition is done on 06Oct, per source. Thank you! ' (Site from CRA).                         | (b) (4), (b) (6)          | 28 Oct 2020 15:50:26 |
| Query 'Please consider updating end date, procedure date for condition is done on 06Oct, per source. Thank you! ' answered with 'updated, thank you' (Site from CRA).  | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:28:23 |
| DataPoint Un-verified.                                                                                                                                                 | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:28:17 |
| User entered '06 Oct 2020' reason for change: Data Entry Error                                                                                                         | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:28:17 |
| DataPoint Verified.                                                                                                                                                    | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User opened query 'Please consider updating end date, procedure date for condition is done on 06Oct, per source. Thank you! ' (Site from CRA).                         | (b) (4), (b) (6)          | 28 Oct 2020 15:27:25 |
| User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).             | System                    | 02 Oct 2020 19:17:12 |
| Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System). | System                    | 02 Oct 2020 19:17:12 |
| User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).                                                                        | System                    | 02 Oct 2020 19:17:12 |
| User entered '1 Oct 2020' reason for change: Data Entry Error                                                                                                          | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:17:12 |
| User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).             | System                    | 02 Oct 2020 19:16:45 |
| User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).                                                                        | System                    | 02 Oct 2020 19:16:45 |
| User entered empty.                                                                                                                                                    | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

End time (00:00-23:59)

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User entered empty. | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |

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**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:35:57

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Severity](#)

| Audit                                          | User                                 | Time (GMT)           |
|------------------------------------------------|--------------------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)                     | 28 Oct 2020 15:27:42 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

| Audit                  | User                      | Time (GMT)           |
|------------------------|---------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User entered 'Yes (Y)' | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Death](#)

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User entered '0'    | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |
|                     | (b) (4)                   |                      |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Life threatening](#)

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User entered '0'    | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User entered '0'    | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |
|                     | (b) (4)                   |                      |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

Hospital Admission Date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                          | User                                 | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                            | (b) (4), (b) (6)                     | 13 Nov 2020 18:11:51 |
| User closed query 'Subject was formally admitted for same day surgery on 06Oct. Please consider updating the entry. ' (Site from CRA).                                                                                                         | (b) (4), (b) (6)                     | 13 Nov 2020 18:11:40 |
| Query 'Subject was formally admitted for same day surgery on 06Oct. Please consider updating the entry. ' answered with 'Subject was not admitted, outpatient surgery performed at the hospital. No admission date required.' (Site from CRA). | Heather Douds (b) (4)<br>(b) (4)     | 13 Nov 2020 16:10:29 |
| DataPoint Un-verified.                                                                                                                                                                                                                         | (b) (4), (b) (6)                     | 13 Nov 2020 15:04:29 |
| User opened query 'Subject was formally admitted for same day surgery on 06Oct. Please consider updating the entry. ' (Site from CRA).                                                                                                         | (b) (4), (b) (6)                     | 13 Nov 2020 15:04:15 |
| DataPoint Verified.                                                                                                                                                                                                                            | (b) (4), (b) (6)                     | 28 Oct 2020 15:27:42 |
| User entered empty.                                                                                                                                                                                                                            | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit                  | User                                 | Time (GMT)           |
|------------------------|--------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                     | 13 Nov 2020 18:11:52 |
| DataPoint Un-verified. | (b) (4), (b) (6)                     | 13 Nov 2020 15:04:27 |
| DataPoint Verified.    | (b) (4), (b) (6)                     | 28 Oct 2020 15:27:42 |
| User entered empty.    | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User entered empty. | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User entered empty. | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Persistent or significant disability or incapacity](#)

| Audit                                                | User                                 | Time (GMT)           |
|------------------------------------------------------|--------------------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)                     | 28 Oct 2020 15:27:42 |
| User entered '0' reason for change: Data Entry Error | Heather Douds (b) (4)                | 02 Oct 2020 20:43:31 |
| User entered '1'                                     | (b) (4)<br>Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Congenital anomaly or birth defect](#)

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User entered '0'    | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |
|                     | (b) (4)                   |                      |

US3552140

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Other medically important event](#)

| Audit                                                | User                                 | Time (GMT)           |
|------------------------------------------------------|--------------------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)                     | 28 Oct 2020 15:27:42 |
| User entered '1' reason for change: Data Entry Error | Heather Douds (b) (4)                | 02 Oct 2020 20:43:31 |
| User entered '0'                                     | (b) (4)<br>Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Relationship to investigational product](#)

| Audit                                                                                  | User                      | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                    | 03 Oct 2020 14:11:31 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                    | 03 Oct 2020 14:11:31 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | Mikayla Frye (b) (4)      | 03 Oct 2020 14:11:31 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)                   |                      |
| User entered empty.                                                                    | System                    | 02 Oct 2020 19:16:45 |
|                                                                                        | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |
|                                                                                        | (b) (4)                   |                      |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Relationship to Study Procedure](#)

| Audit                                                                                  | User                      | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                    | 03 Oct 2020 14:11:31 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                    | 03 Oct 2020 14:11:31 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | Mikayla Frye (b) (4)      | 03 Oct 2020 14:11:31 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)                   |                      |
| User entered empty.                                                                    | System                    | 02 Oct 2020 19:16:45 |
|                                                                                        | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |
|                                                                                        | (b) (4)                   |                      |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

Action taken with investigational product

| Audit                                                                                                                                                                                                                                                                                                                              | User                                          | Time (GMT)                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|----------------------------------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                | (b) (4), (b) (6)                              | 23 Nov 2020 16:23:16                         |
| User closed query 'Please update to Not Applicable. Event started and ended after decision was made not to administer the second dose. ' (Site from CRA).<br>Query 'Please update to Not Applicable. Event started and ended after decision was made not to administer the second dose. ' answered with 'updated' (Site from CRA). | (b) (4), (b) (6)<br>Cassandra Zehenny (b) (4) | 23 Nov 2020 16:23:15<br>23 Nov 2020 15:35:29 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                                             | Cassandra Zehenny (b) (4)                     | 23 Nov 2020 15:35:19                         |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution                                                                                                                                                                                                                                             | Cassandra Zehenny (b) (4)                     | 23 Nov 2020 15:35:19                         |
| User opened query 'Please update to Not Applicable. Event started and ended after decision was made not to administer the second dose. ' (Site from CRA).                                                                                                                                                                          | (b) (4), (b) (6)                              | 22 Nov 2020 16:31:37                         |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                | (b) (4), (b) (6)                              | 28 Oct 2020 15:27:42                         |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                                                                                                                                         | System                                        | 03 Oct 2020 14:11:31                         |
| Query 'Data is required. Please complete.' answered by data change (Site from System).                                                                                                                                                                                                                                             | System                                        | 03 Oct 2020 14:11:31                         |
| User entered 'None (NONE)' reason for change: Data Entry Error                                                                                                                                                                                                                                                                     | Mikayla Frye (b) (4)                          | 03 Oct 2020 14:11:31                         |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                                                                                                                                                                         | (b) (4)                                       | 02 Oct 2020 19:16:45                         |
| User entered empty.                                                                                                                                                                                                                                                                                                                | System                                        | 02 Oct 2020 19:16:45                         |
|                                                                                                                                                                                                                                                                                                                                    | Cassandra Zehenny (b) (4)                     | 02 Oct 2020 19:16:45                         |
|                                                                                                                                                                                                                                                                                                                                    | (b) (4)                                       |                                              |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[None](#)

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User entered '0'    | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |
|                     | (b) (4)                   |                      |

US3552140

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Concomitant Medication](#)

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User entered '1'    | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |

US3552140

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Concomitant Procedure](#)

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User entered '1'    | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |

US3552140

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Outcome](#)

| Audit                                                                                                                                                        | User                                 | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                          | (b) (4), (b) (6)                     | 28 Oct 2020 15:27:42 |
| User closed query 'PV query: Please clarify if the horse shoe retinal tear was a sequela of retinal detachment. Thank you' (Site from Safety).               | (b) (4), (b) (6)                     | 13 Oct 2020 16:45:20 |
| Query 'PV query: Please clarify if the horse shoe retinal tear was a sequela of retinal detachment. Thank you' answered with 'Unrelated' (Site from Safety). | Cassandra Zehenny (b) (4)<br>(b) (4) | 12 Oct 2020 20:22:13 |
| User opened query 'PV query: Please clarify if the horse shoe retinal tear was a sequela of retinal detachment. Thank you' (Site from Safety).               | (b) (4), (b) (6)                     | 12 Oct 2020 15:40:45 |
| Query 'PV query: Please clarify if the horse shoe retinal tear was a sequela of retinal detachment. Thank you, (b) (6)' canceled (Site from Safety).         | (b) (4), (b) (6)                     | 12 Oct 2020 15:40:20 |
| User opened query 'PV query: Please clarify if the horse shoe retinal tear was a sequela of retinal detachment. Thank you, (b) (6)' (Site from Safety).      | (b) (4), (b) (6)                     | 12 Oct 2020 15:39:34 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'                                                                                                       | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:16:45 |

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**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:35:57

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:27:42 |
| User entered empty. | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:16:45 |
|                     | (b) (4)                   |                      |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:35:57

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                             | User                                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)                     | 28 Oct 2020 15:27:42 |
| User closed query 'PV Query: Please provide start date for concomitant medication of hydrochlorothiazide' (Site from Safety).                                                                                                                                                                                                                     | (b) (4), (b) (6)                     | 27 Oct 2020 19:26:00 |
| Query 'PV Query: Please provide start date for concomitant medication of hydrochlorothiazide' answered with 'Date unknown' (Site from Safety).                                                                                                                                                                                                    | (b) (4), (b) (6)                     | 26 Oct 2020 16:58:37 |
| User opened query 'PV Query: Please provide start date for concomitant medication of hydrochlorothiazide' (Site from Safety).                                                                                                                                                                                                                     | (b) (4), (b) (6)                     | 22 Oct 2020 16:28:10 |
| User closed query 'PV query: Please clarify medical history which states" bilateral corneal intacs". Thank you' (Site from Safety).                                                                                                                                                                                                               | (b) (4), (b) (6)                     | 13 Oct 2020 16:45:24 |
| Query 'PV query: Please clarify medical history which states" bilateral corneal intacs". Thank you' answered with 'Corneal lintacs from research study still in place, tears were on bilateral retinas' (Site from Safety).                                                                                                                       | Cassandra Zehenny (b) (4)<br>(b) (4) | 12 Oct 2020 20:22:43 |
| User opened query 'PV query: Please clarify medical history which states" bilateral corneal intacs". Thank you' (Site from Safety).                                                                                                                                                                                                               | (b) (4), (b) (6)                     | 12 Oct 2020 15:40:52 |
| Query 'PV query: Please clarify medical history which states" bilateral corneal intacs". Thank you, (b) (6)' canceled (Site from Safety).                                                                                                                                                                                                         | (b) (4), (b) (6)                     | 12 Oct 2020 15:40:26 |
| User opened query 'PV query: Please clarify medical history which states" bilateral corneal intacs". Thank you, (b) (6) (Site from Safety).                                                                                                                                                                                                       | (b) (4), (b) (6)                     | 12 Oct 2020 15:39:45 |
| User entered 'Subject reported receiving Laser Eye Treatment to fix a Horseshoe Tear of right eye. States she was at her eye doctor for an appointment about her dry eyes and upon exam they found the tear and wanted to fix it. No complications post-procedure. Has taken ibuprofen x2 since procedure for eye pain which has since resolved.' | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:16:45 |

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**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:35:57

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 19:16:45 |

US3552140

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 26 Nov 2020 09:35:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 19:16:45 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 09:35:57**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 05 Nov 2020 20:55:13 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:26:30 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                              | User                      | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| Query 'Please verify if following have been taken by subject. Medication is listed as active in PCP notes. Cevimeline ( Evoxac) 30mg X 3, cylcobenzaprine ( Flexeril) 10mg X 3 oral as needed, hydrocodone-acetaminophen ( Narco) 25mg 7.5-325 mg oral as needed, losartan 100mg once daily, oral hydrochlorthiazide 25mg once daily oral, Savella 100mg X2 daily oral. Thank you ! ' canceled (Site from CRA).    | (b) (4), (b) (6)          | 13 Nov 2020 18:26:50 |
| User opened query 'Please verify if following have been taken by subject. Medication is listed as active in PCP notes. Cevimeline ( Evoxac) 30mg X 3, cylcobenzaprine ( Flexeril) 10mg X 3 oral as needed, hydrocodone-acetaminophen ( Narco) 25mg 7.5-325 mg oral as needed, losartan 100mg once daily, oral hydrochlorthiazide 25mg once daily oral, Savella 100mg X2 daily oral. Thank you ! ' (Site from CRA). | (b) (4), (b) (6)          | 13 Nov 2020 18:26:32 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User closed query 'Per PCP notes page 12 subject to continue taking Restasis, Hydrodiuril and other meds. Please verify if subject is actually taking these meds and update conmed eCRF as needed. Thank you! ' (Site from CRA).                                                                                                                                                                                   | (b) (4), (b) (6)          | 24 Oct 2020 23:19:18 |
| Query 'Per PCP notes page 12 subject to continue taking Restasis, Hydrodiuril and other meds. Please verify if subject is actually taking these meds and update conmed eCRF as needed. Thank you! ' answered with 'Spoke with subject regarding these medications and confirmed her current med list. Con Med sheet is correct as entered. Thank you!' (Site from CRA).                                            | Cassandra Zehenny (b) (4) | 15 Oct 2020 15:21:31 |
| User opened query 'Per PCP notes page 12 subject to continue taking Restasis, Hydrodiuril and other meds. Please verify if subject is actually taking these meds and update conmed eCRF as needed. Thank you! ' (Site from CRA).                                                                                                                                                                                   | (b) (4), (b) (6)          | 15 Oct 2020 01:59:22 |
| Query 'Please update list as needed , per PCP notes page 12 subject to continue taking Restasis, Hydrodiuril and other meds. Please verify if subject is actually taking these meds and they have to be added. ' canceled (Site from CRA).                                                                                                                                                                         | (b) (4), (b) (6)          | 15 Oct 2020 01:58:31 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                  | User                               | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| User opened query 'Please update list as needed , per PCP notes page 12 subject to continue taking Restasis, Hydrodiuril and other meds. Please verify if subject is actually taking these meds and they have to be added. ' (Site from CRA).                                          | (b) (4), (b) (6)                   | 14 Oct 2020 20:26:12 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: COXIBS, PRODUCT:<br>CELECOXIB, PRODUCTSYNONYM: CELEBREX<br>- version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 24 Aug 2020 12:51:33 |
| 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)    | 24 Aug 2020 12:51:33 |
| Data point term sent to Coder                                                                                                                                                                                                                                                          | System                             | 24 Aug 2020 12:30:57 |
| User entered 'celebrex'                                                                                                                                                                                                                                                                | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:30:50 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:30:50 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'rheumatoid' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:30:50 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered '100'  | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:30:50 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'mg (mg)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:30:50 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

[If dose unit is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:30:50 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                            | User                               | Time (GMT)           |
|----------------------------------|------------------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'twice daily (BID)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:30:50 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:30:50 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'Oral (ORAL)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:30:50 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:30:50 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'un UNK 2015' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:30:50 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered '0'    | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:30:50 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Ongoing?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:30:50 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:30:50 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:30:50 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 24 Aug 2020 12:30:50 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 24 Aug 2020 12:30:50 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 24 Aug 2020 12:30:50 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                                      | User                                        | Time (GMT)                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------------------------------|
| DataPoint Verified.                                                                                                                                                                                                        | (b) (4), (b) (6)                            | 28 Oct 2020 15:50:13                         |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC:<br>DIURETICS, ATC: HIGH-CEILING DIURETICS,<br>ATC: SULFONAMIDES, PLAIN, PRODUCT:<br>BUMETANIDE, PRODUCTSYNONYM: BUMEX -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)             | 24 Aug 2020 19:05:57                         |
| 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)             | 24 Aug 2020 19:05:57                         |
| Data point term sent to Coder<br>Coding entries removed.                                                                                                                                                                   | System<br>Heather Douds (b) (4)<br>(b) (4)  | 24 Aug 2020 19:04:38<br>24 Aug 2020 19:03:38 |
| User entered 'Bumex' reason for change: Data Entry<br>Error                                                                                                                                                                | Heather Douds (b) (4)<br>(b) (4)            | 24 Aug 2020 19:03:38                         |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC:<br>DIURETICS, ATC: HIGH-CEILING DIURETICS,<br>ATC: SULFONAMIDES, PLAIN, PRODUCT:<br>BUMETANIDE - version<br>WHODrug-Global-B3\\202003.                        | Coder Import (b) (4)<br>(b) (4)             | 24 Aug 2020 12:33:32                         |
| 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)             | 24 Aug 2020 12:33:32                         |
| Data point term sent to Coder<br>User entered 'bumetanide'                                                                                                                                                                 | System<br>Stanley Dublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:33:02<br>24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                       | User                               | Time (GMT)           |
|-----------------------------|------------------------------------|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'hypertension' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit                                                | User                              | Time (GMT)           |
|------------------------------------------------------|-----------------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)                  | 28 Oct 2020 15:50:13 |
| User entered '1' reason for change: Data Entry Error | Heather Douds (b) (4)             | 24 Aug 2020 19:03:38 |
| User entered '2'                                     | (b) (4)<br>Stanley Dublin (b) (4) | 24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'mg (mg)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

[If dose unit is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'once daily (QD)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'Oral (ORAL)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'un UNK 2012' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered '0'    | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Ongoing?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 24 Aug 2020 12:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 24 Aug 2020 12:32:38 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                                 | User                               | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                   | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User coded data point as ATC: SENSORY<br>ORGANS, ATC: OPHTHALMOLOGICALS, ATC:<br>ANTIGLAUCOMA PREPARATIONS AND<br>MIOTICS, ATC: PARASYMPATHOMIMETICS,<br>PRODUCT: PILOCARPINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 24 Aug 2020 15:39:33 |
| 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)    | 24 Aug 2020 15:39:33 |
| Data point term sent to Coder                                                                                                                                                                                         | System                             | 24 Aug 2020 12:34:03 |
| User entered 'pilocarpine'                                                                                                                                                                                            | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                             | User                               | Time (GMT)           |
|-----------------------------------|------------------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'sjogren's syndrome' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered '5'    | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'mg (mg)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

[If dose unit is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'as needed (PRN)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'Oral (ORAL)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'un UNK 2004' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered '0'    | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

[Ongoing?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:33:51 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:33:51 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                           | User                               | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                             | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: MILNACIPRAN HYDROCHLORIDE, PRODUCTSYNONYM: SAVELLA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 25 Aug 2020 09:35:48 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                                                                                            | Coder Import (b) (4)<br>(b) (4)    | 25 Aug 2020 09:35:48 |
| Data point term sent to Coder                                                                                                                                                                                                                   | System                             | 24 Aug 2020 12:36:07 |
| User entered 'savella'                                                                                                                                                                                                                          | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                       | User                               | Time (GMT)           |
|-----------------------------|------------------------------------|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'fibromyalgia' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered '100'  | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'mg (mg)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

[If dose unit is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                            | User                               | Time (GMT)           |
|----------------------------------|------------------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'twice daily (BID)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'Oral (ORAL)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

[If route of administration is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'un UNK 2008' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered '0'    | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

[Ongoing?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 24 Aug 2020 12:35:35 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 24 Aug 2020 12:35:35 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                     | User                               | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                       | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 24 Aug 2020 12:38:41 |
| 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)    | 24 Aug 2020 12:38:41 |
| Data point term sent to Coder                                                                                                                                                             | System                             | 24 Aug 2020 12:37:08 |
| User entered 'zolpidem'                                                                                                                                                                   | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                   | User                               | Time (GMT)           |
|-------------------------|------------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'insomnia' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit                                                   | User                   | Time (GMT)           |
|---------------------------------------------------------|------------------------|----------------------|
| DataPoint Verified.                                     | (b) (4), (b) (6)       | 28 Oct 2020 15:50:13 |
| User entered '12.5' reason for change: Data Entry Error | Heather Douds (b) (4)  | 24 Aug 2020 19:48:05 |
| User entered '72.5'                                     | Stanley Dublin (b) (4) | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'mg (mg)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

[If dose unit is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'as needed (PRN)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'Oral (ORAL)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'un UNK 2015' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered '0'    | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Ongoing?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:36:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:36:38 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                             | User                                         | Time (GMT)                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|----------------------------------------------|
| DataPoint Verified.                                                                                                                                                                                                                               | (b) (4), (b) (6)                             | 28 Oct 2020 15:50:13                         |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE<br>RELAXANTS, ATC: MUSCLE RELAXANTS,<br>CENTRALLY ACTING AGENTS, ATC: OTHER<br>CENTRALLY ACTING AGENTS, PRODUCT:<br>CYCLOBENZAPRINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)              | 25 Aug 2020 05:55:49                         |
| 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)              | 25 Aug 2020 05:55:49                         |
| Data point term sent to Coder<br>Coding entries removed.                                                                                                                                                                                          | System<br>Heather Douds (b) (4)<br>(b) (4)   | 24 Aug 2020 19:48:53<br>24 Aug 2020 19:48:28 |
| User entered 'CYCLOBENZAPRINE' reason for<br>change: Data Entry Error                                                                                                                                                                             | Heather Douds (b) (4)<br>(b) (4)             | 24 Aug 2020 19:48:28                         |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE<br>RELAXANTS, ATC: MUSCLE RELAXANTS,<br>CENTRALLY ACTING AGENTS, ATC: OTHER<br>CENTRALLY ACTING AGENTS, PRODUCT:<br>CYCLOBENZAPRINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)              | 24 Aug 2020 12:54:35                         |
| 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)              | 24 Aug 2020 12:54:35                         |
| Data point term sent to Coder<br>User entered 'cyclobenzaprine'                                                                                                                                                                                   | System<br>Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:09<br>24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                                                                                                                                                                                                                                                         | User                               | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                           | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User closed query 'Per DM CLR: Please update the indication to specify the location of MUSCLE PAIN DUE TO FIBROMYALGIA. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).                                                  | (b) (4), (b) (6)                   | 27 Oct 2020 05:32:53 |
| Query 'Per DM CLR: Please update the indication to specify the location of MUSCLE PAIN DUE TO FIBROMYALGIA. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'related to fibromyalgia, accurate as entered' (Site from DM). | Heather Douds (b) (4)<br>(b) (4)   | 23 Oct 2020 15:26:45 |
| User opened query 'Per DM CLR: Please update the indication to specify the location of MUSCLE PAIN DUE TO FIBROMYALGIA. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).                                                  | (b) (4), (b) (6)                   | 22 Oct 2020 18:30:30 |
| User entered 'muscle pain due to fibromyalgia'                                                                                                                                                                                                                | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered '10'   | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'mg (mg)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

[If dose unit is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'as needed (PRN)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'Oral (ORAL)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'un UNK 2010' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered '0'    | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

[Ongoing?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:38:07 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:38:07 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                       | User                    | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                         | (b) (4), (b) (6)        | 28 Oct 2020 15:50:13 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 24 Aug 2020 12:39:43 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                                                   | Coder Import (b) (4)    | 24 Aug 2020 12:39:43 |
| Data point term sent to Coder                                                                                                                                                                                                                                                               | System                  | 24 Aug 2020 12:39:09 |
| User entered 'benadryl'                                                                                                                                                                                                                                                                     | Stanley Doublin (b) (4) | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                             | User                               | Time (GMT)           |
|-----------------------------------|------------------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'seasonal allergies' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered '25'   | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'mg (mg)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

[If dose unit is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'as needed (PRN)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'Oral (ORAL)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'un UNK 2000' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered '0'    | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

[Ongoing?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:38:58 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Aug 2020 12:38:58 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                       | User                               | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                         | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 24 Aug 2020 12:40:35 |
| 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)    | 24 Aug 2020 12:40:35 |
| Data point term sent to Coder                                                                                                                                                                                                               | System                             | 24 Aug 2020 12:40:10 |
| User entered 'multivitamin'                                                                                                                                                                                                                 | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                                                      | User                    | Time (GMT)           |
|------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                        | (b) (4), (b) (6)        | 13 Nov 2020 14:38:18 |
| DataPoint Un-verified.                                     | Stanley Doublin (b) (4) | 11 Nov 2020 17:07:31 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Stanley Doublin (b) (4) | 11 Nov 2020 17:07:31 |
| DataPoint Verified.                                        | (b) (4), (b) (6)        | 28 Oct 2020 15:50:13 |
| User entered 'No (N)'                                      | Stanley Doublin (b) (4) | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                           | User                               | Time (GMT)           |
|---------------------------------|------------------------------------|----------------------|
| DataPoint Verified.             | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'health promotion' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered '1'    | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'tablet (TABLET)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

[If dose unit is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'once daily (QD)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'Oral (ORAL)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'un UNK 2000' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered '0'    | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

[Ongoing?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 24 Aug 2020 12:39:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 24 Aug 2020 12:39:37 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                     | User                            | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                       | (b) (4), (b) (6)                | 28 Oct 2020 15:50:13 |
| 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>NIFEDIPINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 05 Sep 2020 18:26:39 |
| 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) | 05 Sep 2020 18:26:39 |
| Data point term sent to Coder                                                                                                                                                                                                                                             | System                          | 05 Sep 2020 18:25:52 |
| User entered 'nifedipine ER'                                                                                                                                                                                                                                              | Joan Siegner (b) (4)<br>(b) (4) | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                 | User                 | Time (GMT)           |
|-----------------------|----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Joan Siegner (b) (4) | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                       | User                 | Time (GMT)           |
|-----------------------------|----------------------|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered 'hypertension' | Joan Siegner (b) (4) | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered '60'   | Joan Siegner (b) (4) | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered 'mg (mg)' | Joan Siegner (b) (4) | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

[If dose unit is Other, specify](#)

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered empty. | Joan Siegner (b) (4) | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                          | User                 | Time (GMT)           |
|--------------------------------|----------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered 'once daily (QD)' | Joan Siegner (b) (4) | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered empty. | Joan Siegner (b) (4) | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered 'Oral (ORAL)' | Joan Siegner (b) (4) | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

[If route of administration is Other, specify](#)

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered empty. | Joan Siegner (b) (4) | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered 'un UNK 2013' | Joan Siegner (b) (4) | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered '0'    | Joan Siegner (b) (4) | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

[Ongoing?](#)

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered 'Yes (Y)' | Joan Siegner (b) (4) | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered empty. | Joan Siegner (b) (4) | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                 | Time (GMT)           |
|-----------------------|----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Joan Siegner (b) (4) | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Sep 2020 18:25:10 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Sep 2020 18:25:10 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                      | User                            | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                        | (b) (4), (b) (6)                | 28 Oct 2020 15:50:13 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: PSYCHOANALEPTICS, ATC:<br>ANTIDEPRESSANTS, ATC: OTHER<br>ANTIDEPRESSANTS, PRODUCT: BUPROPION<br>HYDROCHLORIDE, PRODUCTSYNONYM:<br>WELLBUTRIN - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 05 Sep 2020 18:27:39 |
| 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) | 05 Sep 2020 18:27:39 |
| Data point term sent to Coder                                                                                                                                                                                                              | System                          | 05 Sep 2020 18:26:54 |
| User entered 'Wellbutrin ER'                                                                                                                                                                                                               | Joan Siegner (b) (4)<br>(b) (4) | 05 Sep 2020 18:26:00 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                 | User                 | Time (GMT)           |
|-----------------------|----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Joan Siegner (b) (4) | 05 Sep 2020 18:26:00 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                 | User                                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User closed query 'Per CDM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.<br>' (Site from DM).                                                                                                                     | (b) (4), (b) (6)                     | 30 Oct 2020 05:45:37 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| Query 'Per CDM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.<br>' answered with 'No AE needed. Anxiety is ongoing since 2019, worsened by COVID. Has been on and off Wellbutrin since diagnosis ' (Site from DM). | Cassandra Zehenny (b) (4)<br>(b) (4) | 19 Oct 2020 18:35:36 |
| User opened query 'Per CDM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.<br>' (Site from DM).                                                                                                                     | (b) (4), (b) (6)                     | 19 Oct 2020 10:26:55 |
| User entered 'anxiety'                                                                                                                                                                                                                                                                                                                                                                | Joan Siegner (b) (4)                 | 05 Sep 2020 18:26:00 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered '150'  | Joan Siegner (b) (4) | 05 Sep 2020 18:26:00 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered 'mg (mg)' | Joan Siegner (b) (4) | 05 Sep 2020 18:26:00 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

[If dose unit is Other, specify](#)

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered empty. | Joan Siegner (b) (4) | 05 Sep 2020 18:26:00 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                          | User                 | Time (GMT)           |
|--------------------------------|----------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered 'once daily (QD)' | Joan Siegner (b) (4) | 05 Sep 2020 18:26:00 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered empty. | Joan Siegner (b) (4) | 05 Sep 2020 18:26:00 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered 'Oral (ORAL)' | Joan Siegner (b) (4) | 05 Sep 2020 18:26:00 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered empty. | Joan Siegner (b) (4) | 05 Sep 2020 18:26:00 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                                                         | User                  | Time (GMT)           |
|---------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                           | (b) (4), (b) (6)      | 28 Oct 2020 15:50:13 |
| User entered '09 Sep 2020' reason for change: New Information | Heather Douds (b) (4) | 10 Sep 2020 15:13:14 |
| User entered '05 Sep 2020'                                    | (b) (4)               |                      |
|                                                               | Joan Siegner (b) (4)  | 05 Sep 2020 18:26:00 |
|                                                               |                       |                      |
|                                                               |                       |                      |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered '0'    | Joan Siegner (b) (4) | 05 Sep 2020 18:26:00 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

[Ongoing?](#)

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered 'Yes (Y)' | Joan Siegner (b) (4) | 05 Sep 2020 18:26:00 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered empty. | Joan Siegner (b) (4) | 05 Sep 2020 18:26:00 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                 | Time (GMT)           |
|-----------------------|----------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)     | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Joan Siegner (b) (4) | 05 Sep 2020 18:26:00 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Sep 2020 18:26:00 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Sep 2020 18:26:00 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Sep 2020 18:26:00 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                       | User                             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                         | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User coded data point as ATC: SENSORY<br>ORGANS, ATC: OPHTHALMOLOGICALS, ATC:<br>ANTIINFECTIVES, ATC:<br>FLUOROQUINOLONES, PRODUCT:<br>MOXIFLOXACIN - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 18 Sep 2020 05:51:51 |
| 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)  | 18 Sep 2020 05:51:51 |
| Data point term sent to Coder                                                                                                                                                               | System                           | 17 Sep 2020 20:51:19 |
| User entered 'Moxifloxican'                                                                                                                                                                 | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:50:19 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:50:19 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                             | User                             | Time (GMT)           |
|-----------------------------------|----------------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'retinal detachment' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:50:19 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered '1'    | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:50:19 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'Other (OTHER)' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:50:19 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:57**

[If dose unit is Other, specify](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'drop to L eye' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:50:19 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                                                                     | User                      | Time (GMT)           |
|---------------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                       | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'four times daily (QID)' reason for change: Data Entry Error | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:34:38 |
| User entered 'other (OTHER)'                                              | Heather Douds (b) (4)     | 17 Sep 2020 20:50:19 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:35:57

If frequency is Other, specify

| Audit                                                                                                                                                                                                                                                                       | User                      | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| User closed query 'Per CDM: The Frequency is mentioned as "4X DAILY" Please clarify whether it mean four times daily. If yes, then update the frequency tab as it is one of the listed choices in frequency and other speify as blank.' (Site from DM). DataPoint Verified. | (b) (4), (b) (6)          | 30 Oct 2020 06:51:34 |
|                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| Query 'Per CDM: The Frequency is mentioned as "4X DAILY" Please clarify whether it mean four times daily. If yes, then update the frequency tab as it is one of the listed choices in frequency and other speify as blank.' answered with 'updated' (Site from DM).         | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:34:42 |
|                                                                                                                                                                                                                                                                             | (b) (4)                   |                      |
| User entered empty; reason for change Per Query Resolution                                                                                                                                                                                                                  | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:34:38 |
|                                                                                                                                                                                                                                                                             | (b) (4)                   |                      |
| User opened query 'Per CDM: The Frequency is mentioned as "4X DAILY" Please clarify whether it mean four times daily. If yes, then update the frequency tab as it is one of the listed choices in frequency and other speify as blank.' (Site from DM).                     | (b) (4), (b) (6)          | 28 Oct 2020 12:57:50 |
|                                                                                                                                                                                                                                                                             |                           |                      |
| User entered '4x daily'                                                                                                                                                                                                                                                     | Heather Douds (b) (4)     | 17 Sep 2020 20:50:19 |
|                                                                                                                                                                                                                                                                             | (b) (4)                   |                      |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                                                                                  | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)      | 28 Oct 2020 15:50:13 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                | 17 Sep 2020 20:50:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 17 Sep 2020 20:50:46 |
| User entered 'Intraocular (INTRAOCULAR)' reason for change: Data Entry Error           | Heather Douds (b) (4) | 17 Sep 2020 20:50:46 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                | 17 Sep 2020 20:50:19 |
| User entered empty.                                                                    | Heather Douds (b) (4) | 17 Sep 2020 20:50:19 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:50:19 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered '11 Sep 2020' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:50:19 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered '0'    | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:50:19 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:35:57

[Ongoing?](#)

| Audit                                                                                                                                                                                                                                                                                      | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User closed query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).             | (b) (4), (b) (6)                 | 28 Oct 2020 05:49:18 |
| Query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM). | Heather Douds (b) (4)<br>(b) (4) | 23 Oct 2020 15:27:56 |
| User entered 'No (N)' reason for change: New Information                                                                                                                                                                                                                                   | Heather Douds (b) (4)<br>(b) (4) | 23 Oct 2020 15:27:51 |
| User opened query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).             | (b) (4), (b) (6)                 | 23 Oct 2020 07:02:27 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                                     | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:50:19 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:57**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                                                         | User                  | Time (GMT)           |
|---------------------------------------------------------------|-----------------------|----------------------|
| DataPoint Verified.                                           | (b) (4), (b) (6)      | 28 Oct 2020 15:50:13 |
| User entered '18 Sep 2020' reason for change: New Information | Heather Douds (b) (4) | 23 Oct 2020 15:27:51 |
| User entered empty.                                           | Heather Douds (b) (4) | 17 Sep 2020 20:50:19 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:50:19 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '4'    | System | 28 Oct 2020 15:34:38 |
| User entered empty. | System | 17 Sep 2020 20:50:19 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1'    | System | 28 Oct 2020 15:34:38 |
| User entered empty. | System | 17 Sep 2020 20:50:19 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 28 Oct 2020 15:34:38 |
| User entered empty.      | System | 17 Sep 2020 20:50:19 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                              | User                             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User coded data point as ATC: SENSORY<br>ORGANS, ATC: OPHTHALMOLOGICALS, ATC:<br>ANTIINFLAMMATORY AGENTS, ATC:<br>CORTICOSTEROIDS, PLAIN, PRODUCT:<br>PREDNISOLONE ACETATE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 18 Sep 2020 05:36:51 |
| 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)  | 18 Sep 2020 05:36:51 |
| Data point term sent to Coder                                                                                                                                                                                      | System                           | 17 Sep 2020 20:52:20 |
| User entered 'Prednisolone acetate'                                                                                                                                                                                | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:51:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:51:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                             | User                             | Time (GMT)           |
|-----------------------------------|----------------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'retinal detachment' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:51:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit                                                | User                      | Time (GMT)           |
|------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)          | 06 Nov 2020 17:17:48 |
| User entered '1' reason for change: Data Entry Error | Cassandra Zehenny (b) (4) | 05 Nov 2020 15:26:54 |
| DataPoint Un-verified.                               | (b) (4)                   |                      |
|                                                      | Cassandra Zehenny (b) (4) | 05 Nov 2020 15:26:12 |
|                                                      | (b) (4)                   |                      |
| User entered '2' reason for change: Data Entry Error | Cassandra Zehenny (b) (4) | 05 Nov 2020 15:26:12 |
|                                                      | (b) (4)                   |                      |
| DataPoint Verified.                                  | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered '1'                                     | Heather Douds (b) (4)     | 17 Sep 2020 20:51:54 |
|                                                      | (b) (4)                   |                      |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'Other (OTHER)' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:51:54 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:35:57

If dose unit is Other, specify

| Audit                                                               | User                      | Time (GMT)           |
|---------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                 | (b) (4), (b) (6)          | 06 Nov 2020 17:17:58 |
| User entered 'DROP' reason for change: Data Entry Error             | Cassandra Zehenny (b) (4) | 05 Nov 2020 15:26:54 |
| DataPoint Un-verified.                                              | (b) (4)                   |                      |
|                                                                     | Cassandra Zehenny (b) (4) | 05 Nov 2020 15:26:12 |
| User entered 'DROPS' reason for change: Data Entry Error            | (b) (4)                   |                      |
|                                                                     | Cassandra Zehenny (b) (4) | 05 Nov 2020 15:26:12 |
| DataPoint Verified.                                                 | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'DROP TO L EYE 3X' reason for change: Data Entry Error | Heather Douds (b) (4)     | 23 Oct 2020 15:28:31 |
| User entered 'drop to L eye 4x'                                     | (b) (4)                   |                      |
|                                                                     | Heather Douds (b) (4)     | 17 Sep 2020 20:51:54 |
|                                                                     | (b) (4)                   |                      |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:35:57

[Frequency](#)

| Audit                                                                                                                                                                                                                                                                                                                                                 | User                      | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| User closed query 'Per DM CLR: It was noted in the response that it was "FOUR TIMES DAILY". However, the update is only three times daily. Note that "FOUR TIMES DAILY" is also available in the list of options for frequency. Please verify data and update as appropriate.' (Site from DM).                                                        | (b) (4), (b) (6)          | 13 Nov 2020 08:11:38 |
| Query 'Per DM CLR: It was noted in the response that it was "FOUR TIMES DAILY". However, the update is only three times daily. Note that "FOUR TIMES DAILY" is also available in the list of options for frequency. Please verify data and update as appropriate.' answered with 'Dosage has been decreased, data correct as entered' (Site from DM). | Cassandra Zehenny (b) (4) | 11 Nov 2020 19:28:36 |
| User opened query 'Per DM CLR: It was noted in the response that it was "FOUR TIMES DAILY". However, the update is only three times daily. Note that "FOUR TIMES DAILY" is also available in the list of options for frequency. Please verify data and update as appropriate.' (Site from DM).                                                        | (b) (4), (b) (6)          | 11 Nov 2020 15:26:01 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)          | 06 Nov 2020 17:17:44 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                                                                | Cassandra Zehenny (b) (4) | 05 Nov 2020 15:26:54 |
| User entered 'three times daily (TID)' reason for change: Data Entry Error                                                                                                                                                                                                                                                                            | Cassandra Zehenny (b) (4) | 05 Nov 2020 15:26:54 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'other (OTHER)'                                                                                                                                                                                                                                                                                                                          | Heather Douds (b) (4)     | 17 Sep 2020 20:51:54 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:35:57

If frequency is Other, specify

| Audit                                                                                                                                                                                                                                                                                                                  | User                      | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                    | (b) (4), (b) (6)          | 06 Nov 2020 17:17:40 |
| User closed query 'Per CDM: Thank you for the response. The "four times daily" is the one of the listed choices in the frequency. Kindly, update the data field and keep other specify blank. ' (Site from DM).                                                                                                        | (b) (4), (b) (6)          | 06 Nov 2020 02:06:58 |
| Query 'Per CDM: Thank you for the response. The "four times daily" is the one of the listed choices in the frequency. Kindly, update the data field and keep other specify blank. ' answered with 'updated' (Site from DM).                                                                                            | Cassandra Zehenny (b) (4) | 05 Nov 2020 15:27:01 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                                 | Cassandra Zehenny (b) (4) | 05 Nov 2020 15:26:54 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                                                                                                                                 | Cassandra Zehenny (b) (4) | 05 Nov 2020 15:26:54 |
| User opened query 'Per CDM: Thank you for the response. The "four times daily" is the one of the listed choices in the frequency. Kindly, update the data field and keep other specify blank. ' (Site from DM).                                                                                                        | (b) (4), (b) (6)          | 05 Nov 2020 06:02:22 |
| User closed query 'Per DM CLR: Please review "Other Frequency" as there is an available option for "Once Daily" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).                                      | (b) (4), (b) (6)          | 05 Nov 2020 06:00:47 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                    | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| Query 'Per DM CLR: Please review "Other Frequency" as there is an available option for "Once Daily" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'four times daily, not just daily' (Site from DM). | Heather Douds (b) (4)     | 23 Oct 2020 15:28:16 |
| User opened query 'Per DM CLR: Please review "Other Frequency" as there is an available option for "Once Daily" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).                                      | (b) (4), (b) (6)          | 23 Oct 2020 07:03:06 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit                | User                             | Time (GMT)           |
|----------------------|----------------------------------|----------------------|
| User entered 'daily' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:51:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                                    | User                             | Time (GMT)           |
|------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'Intraocular (INTRAOCULAR)' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:51:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:51:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered '11 Sep 2020' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:51:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered '0'    | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:51:54 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:35:57

[Ongoing?](#)

| Audit                                                                                                                                                                                                                                                                                           | User                             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User closed query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).                   | (b) (4), (b) (6)                 | 28 Oct 2020 05:49:38 |
| Query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' answered with 'still ongoing' (Site from DM). | Heather Douds (b) (4)<br>(b) (4) | 23 Oct 2020 15:32:51 |
| User opened query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).                   | (b) (4), (b) (6)                 | 23 Oct 2020 07:03:16 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                                          | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:51:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:57**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:51:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:51:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '3'    | System | 05 Nov 2020 15:26:54 |
| User entered empty. | System | 17 Sep 2020 20:51:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1'    | System | 05 Nov 2020 15:26:54 |
| User entered empty. | System | 17 Sep 2020 20:51:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Nov 2020 15:26:54 |
| User entered empty.      | System | 17 Sep 2020 20:51:54 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                                                          | User                                 | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User closed query 'Please add Restasis, Savella, Cozaar per PCP note on current meds ( page 12 of PCP report). ' (Site from CRA).                                                                                                                                                                                              | (b) (4), (b) (6)                     | 06 Nov 2020 17:18:17 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                            | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| Query 'Please add Restasis, Savella, Cozaar per PCP note on current meds ( page 12 of PCP report). ' answered with 'attempting to reach volunteer to confirm that these are actually current medications since they were not reported in visits 1 or 2. will update once we have more information. Thank you' (Site from CRA). | Cassandra Zehenny (b) (4)<br>(b) (4) | 01 Oct 2020 19:26:59 |
| User opened query 'Please add Restasis, Savella, Cozaar per PCP note on current meds ( page 12 of PCP report). ' (Site from CRA).                                                                                                                                                                                              | (b) (4), (b) (6)                     | 30 Sep 2020 15:29:51 |
| User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: MYDRIATICS AND CYCLOPLEGICS, ATC: ANTICHOLINERGICS, PRODUCT: CYCLOPENTOLATE - version WHODrug-Global-B3\\202003.                                                                                                                                    | Coder Import (b) (4)<br>(b) (4)      | 18 Sep 2020 06:30:48 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                                                                                                                                                                           | Coder Import (b) (4)<br>(b) (4)      | 18 Sep 2020 06:30:48 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                  | System                               | 17 Sep 2020 20:53:21 |
| User entered 'Cyclopentolate 1%'                                                                                                                                                                                                                                                                                               | Heather Douds (b) (4)<br>(b) (4)     | 17 Sep 2020 20:52:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:52:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                             | User                             | Time (GMT)           |
|-----------------------------------|----------------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'retinal detachment' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:52:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered '1'    | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:52:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'Other (OTHER)' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:52:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:57**

[If dose unit is Other, specify](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'drop to L eye' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:52:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                            | User                             | Time (GMT)           |
|----------------------------------|----------------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'twice daily (BID)' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:52:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:52:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                                    | User                             | Time (GMT)           |
|------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'Intraocular (INTRAOCULAR)' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:52:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:52:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered '12 Sep 2020' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:52:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered '0'    | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:52:37 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:35:57

[Ongoing?](#)

| Audit                                                                                                                                                                                                                                                                                                                     | User                             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User closed query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).                                            | (b) (4), (b) (6)                 | 28 Oct 2020 05:49:56 |
| Query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'still ongoing at this time per subject' (Site from DM). | Heather Douds (b) (4)<br>(b) (4) | 23 Oct 2020 15:34:19 |
| User opened query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).                                            | (b) (4), (b) (6)                 | 23 Oct 2020 07:03:53 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                                                                    | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:52:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:57**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:52:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                             | Time (GMT)           |
|-----------------------|----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                 | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:52:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 17 Sep 2020 20:52:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Sep 2020 20:52:37 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 17 Sep 2020 20:52:37 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                               | User                                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                 | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC:<br>DIURETICS, ATC: LOW-CEILING DIURETICS,<br>THIAZIDES, ATC: THIAZIDES, PLAIN,<br>PRODUCT: HYDROCHLOROTHIAZIDE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 02 Oct 2020 18:55:44 |
| 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)      | 02 Oct 2020 18:55:44 |
| Data point term sent to Coder                                                                                                                                                                                       | System                               | 02 Oct 2020 18:55:17 |
| User entered 'Hydrochlorothiazide'                                                                                                                                                                                  | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 18:54:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                 | User                                 | Time (GMT)           |
|-----------------------|--------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 18:54:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                       | User                                 | Time (GMT)           |
|-----------------------------|--------------------------------------|----------------------|
| DataPoint Verified.         | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered 'Hypertension' | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 18:54:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit               | User                                 | Time (GMT)           |
|---------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered '25'   | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 18:54:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                  | User                                 | Time (GMT)           |
|------------------------|--------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered 'mg (mg)' | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 18:54:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

[If dose unit is Other, specify](#)

| Audit               | User                                 | Time (GMT)           |
|---------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered empty. | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 18:54:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                          | User                      | Time (GMT)           |
|--------------------------------|---------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'once daily (QD)' | Cassandra Zehenny (b) (4) | 02 Oct 2020 18:54:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                                 | Time (GMT)           |
|---------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered empty. | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 18:54:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                      | User                      | Time (GMT)           |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'Oral (ORAL)' | Cassandra Zehenny (b) (4) | 02 Oct 2020 18:54:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered empty. | Cassandra Zehenny (b) (4) | 02 Oct 2020 18:54:54 |
|                     | (b) (4)                   |                      |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                                 | Time (GMT)           |
|---------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered empty. | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 18:54:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit                  | User                                 | Time (GMT)           |
|------------------------|--------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                     | 13 Nov 2020 14:50:35 |
| DataPoint Un-verified. | (b) (4), (b) (6)                     | 13 Nov 2020 14:46:05 |
| DataPoint Verified.    | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered '1'       | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 18:54:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

[Ongoing?](#)

| Audit                  | User                                 | Time (GMT)           |
|------------------------|--------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered 'Yes (Y)' | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 18:54:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered empty. | Cassandra Zehenny (b) (4) | 02 Oct 2020 18:54:54 |
|                     | (b) (4)                   |                      |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                      | Time (GMT)           |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4) | 02 Oct 2020 18:54:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 18:54:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 18:54:54 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 02 Oct 2020 18:54:54 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                  | User                                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| 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>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 03 Oct 2020 07:34:38 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.                                                                                                                                                                             | Coder Import (b) (4)<br>(b) (4)      | 03 Oct 2020 07:34:38 |
| Data point term sent to Coder                                                                                                                                                                                                                                                          | System                               | 02 Oct 2020 19:20:04 |
| User entered 'Ibuprofen'                                                                                                                                                                                                                                                               | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:19:21 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                                                                                                   | User                      | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                                                     | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User closed query 'Please add meds administered during procedure on 06Oct' (Site from CRA).             | (b) (4), (b) (6)          | 28 Oct 2020 15:49:19 |
| Query 'Please add meds administered during procedure on 06Oct' answered with 'updated' (Site from CRA). | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:34:53 |
| User opened query 'Please add meds administered during procedure on 06Oct' (Site from CRA).             | (b) (4), (b) (6)          | 28 Oct 2020 15:22:06 |
| User entered 'No (N)'                                                                                   | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:19:21 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                                            | User                                 | Time (GMT)           |
|--------------------------------------------------|--------------------------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered 'Eye pain related to eye procedure' | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:19:21 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit               | User                                 | Time (GMT)           |
|---------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered '600'  | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:19:21 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                  | User                                 | Time (GMT)           |
|------------------------|--------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered 'mg (mg)' | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:19:21 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:35:57**

If dose unit is Other, specify

| Audit               | User                                 | Time (GMT)           |
|---------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered empty. | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:19:21 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                          | User                      | Time (GMT)           |
|--------------------------------|---------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'as needed (PRN)' | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:19:21 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                                 | Time (GMT)           |
|---------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered empty. | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:19:21 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                      | User                      | Time (GMT)           |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'Oral (ORAL)' | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:19:21 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit               | User                                 | Time (GMT)           |
|---------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered empty. | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:19:21 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:35:57

Start date (dd MMM yyyy)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 11 Nov 2020 14:51:44 |
| DataPoint Un-verified.                                         | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:35:30 |
| User entered '01 Oct 2020' reason for change: Data Entry Error | (b) (4)                   |                      |
|                                                                | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:35:30 |
| DataPoint Verified.                                            | (b) (4)                   |                      |
|                                                                | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered '1 Oct 2020'                                      | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:19:21 |
|                                                                | (b) (4)                   |                      |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered '0'    | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:19:21 |
|                     | (b) (4)                   |                      |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:35:57**

[Ongoing?](#)

| Audit                 | User                      | Time (GMT)           |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:19:21 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:35:57**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 11 Nov 2020 14:51:46 |
| DataPoint Un-verified.                                         | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:35:30 |
| User entered '02 Oct 2020' reason for change: Data Entry Error | (b) (4)                   |                      |
|                                                                | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:35:30 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered '2 Oct 2020'                                      | Cassandra Zehenny (b) (4) | 02 Oct 2020 19:19:21 |
|                                                                | (b) (4)                   |                      |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                                 | Time (GMT)           |
|-----------------------|--------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4)<br>(b) (4) | 02 Oct 2020 19:19:21 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Oct 2020 19:19:21 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Oct 2020 19:19:21 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Oct 2020 19:19:21 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                      | User                                 | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User coded data point as ATC: SENSORY<br>ORGANS, ATC: OPHTHALMOLOGICALS, ATC:<br>MYDRIATICS AND CYCLOPLEGICS, ATC:<br>ANTICHOLINERGICS, PRODUCT:<br>CYCLOPENTOLATE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 30 Oct 2020 03:28:02 |
| 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)      | 30 Oct 2020 03:28:02 |
| DataPoint Verified.                                                                                                                                                                                        | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| Data point term sent to Coder                                                                                                                                                                              | System                               | 28 Oct 2020 15:31:55 |
| User entered 'Cyclopentolate 2%'                                                                                                                                                                           | Cassandra Zehenny (b) (4)<br>(b) (4) | 28 Oct 2020 15:31:31 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                 | User                      | Time (GMT)           |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:31:31 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                                   | User                                 | Time (GMT)           |
|-----------------------------------------|--------------------------------------|----------------------|
| DataPoint Verified.                     | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered 'Cryotherapy of right eye' | Cassandra Zehenny (b) (4)<br>(b) (4) | 28 Oct 2020 15:31:31 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit               | User                                 | Time (GMT)           |
|---------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered '1'    | Cassandra Zehenny (b) (4)<br>(b) (4) | 28 Oct 2020 15:31:31 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                        | User                      | Time (GMT)           |
|------------------------------|---------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'Other (OTHER)' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:31:31 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:35:57**

[If dose unit is Other, specify](#)

| Audit                            | User                      | Time (GMT)           |
|----------------------------------|---------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'drop in right eye' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:31:31 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                          | User                      | Time (GMT)           |
|--------------------------------|---------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'as needed (PRN)' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:31:31 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                                 | Time (GMT)           |
|---------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered empty. | Cassandra Zehenny (b) (4)<br>(b) (4) | 28 Oct 2020 15:31:31 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                        | User                      | Time (GMT)           |
|------------------------------|---------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'Other (OTHER)' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:31:31 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit                              | User                      | Time (GMT)           |
|------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'ophthalmic solution' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:31:31 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:35:57

Start date (dd MMM yyyy)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 11 Nov 2020 14:51:56 |
| DataPoint Un-verified.                                         | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:35:42 |
| User entered '06 Oct 2020' reason for change: Data Entry Error | (b) (4)                   |                      |
|                                                                | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:35:42 |
| DataPoint Verified.                                            | (b) (4)                   |                      |
|                                                                | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered '6 Oct 2020'                                      | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:31:31 |
|                                                                | (b) (4)                   |                      |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered '0'    | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:31:31 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:35:57**

[Ongoing?](#)

| Audit                 | User                      | Time (GMT)           |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:31:31 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:35:57

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 11 Nov 2020 14:51:58 |
| DataPoint Un-verified.                                         | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:35:42 |
| User entered '06 Oct 2020' reason for change: Data Entry Error | (b) (4)                   |                      |
|                                                                | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:35:42 |
| DataPoint Verified.                                            | (b) (4)                   |                      |
|                                                                | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered '6 Oct 2020'                                      | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:31:31 |
|                                                                | (b) (4)                   |                      |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                      | Time (GMT)           |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:31:31 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 15:31:31 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 15:31:31 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 15:31:31 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                        | User                                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User coded data point as ATC: SENSORY<br>ORGANS, ATC: OPHTHALMOLOGICALS, ATC:<br>MYDRIATICS AND CYCLOPLEGICS, ATC:<br>SYMPATHOMIMETICS EXCL.<br>ANTIGLAUCOMA PREPARATIONS, PRODUCT:<br>PHENYLEPHRINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 29 Oct 2020 18:08:15 |
| 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)      | 29 Oct 2020 18:08:15 |
| DataPoint Verified.                                                                                                                                                                                                                          | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| Data point term sent to Coder                                                                                                                                                                                                                | System                               | 28 Oct 2020 15:32:56 |
| User entered 'Phenylephrine 2.5%'                                                                                                                                                                                                            | Cassandra Zehenny (b) (4)<br>(b) (4) | 28 Oct 2020 15:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                 | User                      | Time (GMT)           |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:32:38 |
|                       | (b) (4)                   |                      |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                                   | User                                 | Time (GMT)           |
|-----------------------------------------|--------------------------------------|----------------------|
| DataPoint Verified.                     | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered 'Cryotherapy of right eye' | Cassandra Zehenny (b) (4)<br>(b) (4) | 28 Oct 2020 15:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit               | User                                 | Time (GMT)           |
|---------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered '1'    | Cassandra Zehenny (b) (4)<br>(b) (4) | 28 Oct 2020 15:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                        | User                                 | Time (GMT)           |
|------------------------------|--------------------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered 'Other (OTHER)' | Cassandra Zehenny (b) (4)<br>(b) (4) | 28 Oct 2020 15:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:35:57**

[If dose unit is Other, specify](#)

| Audit                            | User                      | Time (GMT)           |
|----------------------------------|---------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'drop in right eye' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                          | User                      | Time (GMT)           |
|--------------------------------|---------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'as needed (PRN)' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                                 | Time (GMT)           |
|---------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered empty. | Cassandra Zehenny (b) (4)<br>(b) (4) | 28 Oct 2020 15:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                        | User                      | Time (GMT)           |
|------------------------------|---------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'Other (OTHER)' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit                              | User                      | Time (GMT)           |
|------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'ophthalmic solution' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:32:38 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:35:57

Start date (dd MMM yyyy)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 11 Nov 2020 14:52:05 |
| DataPoint Un-verified.                                         | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:35:52 |
| User entered '06 Oct 2020' reason for change: Data Entry Error | (b) (4)                   |                      |
|                                                                | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:35:52 |
| DataPoint Verified.                                            | (b) (4)                   |                      |
|                                                                | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered '6 Oct 2020'                                      | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:32:38 |
|                                                                | (b) (4)                   |                      |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered '0'    | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:35:57**

[Ongoing?](#)

| Audit                 | User                                 | Time (GMT)           |
|-----------------------|--------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4)<br>(b) (4) | 28 Oct 2020 15:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:35:57**

**If not Ongoing, End date (dd MMM yyyy)**

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 11 Nov 2020 14:52:07 |
| DataPoint Un-verified.                                         | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:35:52 |
| User entered '06 Oct 2020' reason for change: Data Entry Error | (b) (4)                   |                      |
|                                                                | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:35:52 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered '6 Oct 2020'                                      | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:32:38 |
|                                                                | (b) (4)                   |                      |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                      | Time (GMT)           |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 15:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 15:32:38 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 15:32:38 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:35:57

[Name of Medication](#)

| Audit                                                                                                                                                                                                   | User                                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User coded data point as ATC: SENSORY<br>ORGANS, ATC: OPHTHALMOLOGICALS, ATC:<br>MYDRIATICS AND CYCLOPLEGICS, ATC:<br>ANTICHOLINERGICS, PRODUCT:<br>TROPICAMIDE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 29 Oct 2020 18:21:13 |
| 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)      | 29 Oct 2020 18:21:13 |
| DataPoint Verified.                                                                                                                                                                                     | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| Data point term sent to Coder                                                                                                                                                                           | System                               | 28 Oct 2020 15:34:58 |
| User entered 'tropicamide 1%'                                                                                                                                                                           | Cassandra Zehenny (b) (4)<br>(b) (4) | 28 Oct 2020 15:33:59 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                 | User                      | Time (GMT)           |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:33:59 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                                   | User                                 | Time (GMT)           |
|-----------------------------------------|--------------------------------------|----------------------|
| DataPoint Verified.                     | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered 'Cryotherapy of right eye' | Cassandra Zehenny (b) (4)<br>(b) (4) | 28 Oct 2020 15:33:59 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit               | User                                 | Time (GMT)           |
|---------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered '1'    | Cassandra Zehenny (b) (4)<br>(b) (4) | 28 Oct 2020 15:33:59 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                        | User                      | Time (GMT)           |
|------------------------------|---------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'Other (OTHER)' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:33:59 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:35:57**

If dose unit is Other, specify

| Audit                            | User                      | Time (GMT)           |
|----------------------------------|---------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'drop in right eye' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:33:59 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                          | User                      | Time (GMT)           |
|--------------------------------|---------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'as needed (PRN)' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:33:59 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                                 | Time (GMT)           |
|---------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                     | 28 Oct 2020 15:50:13 |
| User entered empty. | Cassandra Zehenny (b) (4)<br>(b) (4) | 28 Oct 2020 15:33:59 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                        | User                      | Time (GMT)           |
|------------------------------|---------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'Other (OTHER)' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:33:59 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit                              | User                      | Time (GMT)           |
|------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'ophthalmic solution' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:33:59 |
|                                    | (b) (4)                   |                      |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:35:57

Start date (dd MMM yyyy)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 11 Nov 2020 14:52:15 |
| DataPoint Un-verified.                                         | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:36:02 |
| User entered '06 Oct 2020' reason for change: Data Entry Error | (b) (4)                   |                      |
|                                                                | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:36:02 |
| DataPoint Verified.                                            | (b) (4)                   |                      |
|                                                                | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered '6 Oct 2020'                                      | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:33:59 |
|                                                                | (b) (4)                   |                      |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                      | Time (GMT)           |
|---------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered '0'    | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:33:59 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:35:57**

[Ongoing?](#)

| Audit                 | User                      | Time (GMT)           |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:33:59 |

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:35:57

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 11 Nov 2020 14:52:17 |
| DataPoint Un-verified.                                         | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:36:02 |
| User entered '06 Oct 2020' reason for change: Data Entry Error | (b) (4)                   |                      |
|                                                                | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:36:02 |
| DataPoint Verified.                                            | (b) (4)                   |                      |
|                                                                | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered '6 Oct 2020'                                      | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:33:59 |
|                                                                | (b) (4)                   |                      |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                      | Time (GMT)           |
|-----------------------|---------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)          | 28 Oct 2020 15:50:13 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4) | 28 Oct 2020 15:33:59 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 15:33:59 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 15:33:59 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 15:33:59 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Name of Medication](#)

| Audit                                                                                                                                                                                       | User                               | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                         | (b) (4), (b) (6)                   | 23 Nov 2020 16:24:21 |
| 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)    | 19 Nov 2020 13:12:57 |
| 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)    | 19 Nov 2020 13:12:57 |
| Data point term sent to Coder                                                                                                                                                               | System                             | 19 Nov 2020 13:12:05 |
| User entered 'influenza vaccine'                                                                                                                                                            | Stanley Doublin (b) (4)<br>(b) (4) | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Prophylaxis](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                   | 23 Nov 2020 16:24:35 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4)<br>(b) (4) | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                                | User                               | Time (GMT)           |
|--------------------------------------|------------------------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6)                   | 23 Nov 2020 16:24:37 |
| User entered 'influenza prophylaxis' | Stanley Doublin (b) (4)<br>(b) (4) | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose per administration](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 23 Nov 2020 16:24:39 |
| User entered '1'    | Stanley Doublin (b) (4)<br>(b) (4) | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Dose unit](#)

| Audit                        | User                               | Time (GMT)           |
|------------------------------|------------------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)                   | 23 Nov 2020 16:24:40 |
| User entered 'Other (OTHER)' | Stanley Doublin (b) (4)<br>(b) (4) | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

[If dose unit is Other, specify](#)

| Audit                    | User                               | Time (GMT)           |
|--------------------------|------------------------------------|----------------------|
| DataPoint Verified.      | (b) (4), (b) (6)                   | 23 Nov 2020 16:24:42 |
| User entered 'injection' | Stanley Doublin (b) (4)<br>(b) (4) | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Frequency](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                  | 23 Nov 2020 16:24:43 |
| User entered 'once (ONCE)' | Stanley Dublin (b) (4)<br>(b) (4) | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

[If frequency is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 23 Nov 2020 16:24:44 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Route of administration](#)

| Audit                                        | User                               | Time (GMT)           |
|----------------------------------------------|------------------------------------|----------------------|
| DataPoint Verified.                          | (b) (4), (b) (6)                   | 23 Nov 2020 16:24:46 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | Stanley Doublin (b) (4)<br>(b) (4) | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

If route of administration is Other, specify

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 23 Nov 2020 16:24:47 |
| User entered empty. | Stanley Doublin (b) (4)<br>(b) (4) | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 23 Nov 2020 16:24:49 |
| User entered '17 Nov 2020' | Stanley Doublin (b) (4)<br>(b) (4) | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Start date completely unknown](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                   | 23 Nov 2020 16:24:51 |
| User entered '0'    | Stanley Doublin (b) (4)<br>(b) (4) | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Ongoing?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 23 Nov 2020 16:24:53 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 23 Nov 2020 16:24:54 |
| User entered '17 Nov 2020' | Stanley Doublin (b) (4)<br>(b) (4) | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Was this medication taken for solicited event?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                   | 23 Nov 2020 16:24:55 |
| User entered 'No (N)' | Stanley Doublin (b) (4)<br>(b) (4) | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 09:35:57**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Nov 2020 13:11:55 |

US3552140

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 09:35:57**

[Were any concomitant procedures performed?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                 | 09 Nov 2020 15:41:03 |
| User entered 'Yes (Y)' | Heather Douds (b) (4)<br>(b) (4) | 12 Sep 2020 16:12:25 |

US3552140

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 14 Oct 2020 20:34:17 |
| User entered '11 Sep 2020' | Heather Douds (b) (4)<br>(b) (4) | 12 Sep 2020 16:12:47 |

US3552140

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Procedure/Surgery](#)

| Audit                                                                                                                  | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                                    | (b) (4), (b) (6)                 | 14 Oct 2020 20:34:19 |
| User entered 'LEFT EYE Vitrectomy<br>Membranectomy [retinal detachment repair]' reason<br>for change: Data Entry Error | Heather Douds (b) (4)<br>(b) (4) | 17 Sep 2020 20:20:16 |
| User entered 'Left eye retinal detachment repair'                                                                      | Heather Douds (b) (4)<br>(b) (4) | 12 Sep 2020 16:12:47 |

US3552140

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                             | User                             | Time (GMT)           |
|-----------------------------------|----------------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)                 | 14 Oct 2020 20:34:20 |
| User entered 'Adverse Event (AE)' | Heather Douds (b) (4)<br>(b) (4) | 12 Sep 2020 16:12:47 |

US3552140

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:35:57**

[If indication is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 14 Oct 2020 20:34:21 |
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 12 Sep 2020 16:12:47 |

US3552140

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

| Audit                                                                                      | User                      | Time (GMT)           |
|--------------------------------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                                        | (b) (4), (b) (6)          | 11 Nov 2020 14:53:37 |
| DataPoint Un-verified.                                                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:36:21 |
| User entered '01 Oct 2020' reason for change: Data Entry Error                             | (b) (4)                   |                      |
|                                                                                            | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:36:21 |
| DataPoint Verified.                                                                        | (b) (4)                   |                      |
|                                                                                            | (b) (4), (b) (6)          | 28 Oct 2020 15:26:20 |
| Query 'Please verify the date. Should it be 06Oct, per PCP. ' canceled (Site from CRA).    | (b) (4), (b) (6)          | 14 Oct 2020 20:42:20 |
| User opened query 'Please verify the date. Should it be 06Oct, per PCP. ' (Site from CRA). | (b) (4), (b) (6)          | 14 Oct 2020 20:38:02 |
| User entered '1 Oct 2020'                                                                  | Heather Douds (b) (4)     | 02 Oct 2020 20:43:56 |
|                                                                                            | (b) (4)                   |                      |

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:35:57

[Procedure/Surgery](#)

| Audit                                                                                                                                                                                                                                                                                             | User                      | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)          | 28 Oct 2020 15:26:20 |
| User closed query 'Cryotherapy of right eye was done on 06Oct. Please add procedure to this eCRF. No source for Laser repair of right retial horsehoe tear done on 01Oct. Please provide to verify this procedure. ' (Site from CRA).                                                             | (b) (4), (b) (6)          | 18 Oct 2020 02:17:19 |
| Query 'Cryotherapy of right eye was done on 06Oct. Please add procedure to this eCRF. No source for Laser repair of right retial horsehoe tear done on 01Oct. Please provide to verify this procedure. ' answered with 'Sorry for the incorrect data entry. Updated. Thank you!' (Site from CRA). | Cassandra Zehenny (b) (4) | 15 Oct 2020 15:24:16 |
| User entered 'LASER photocoagulation REPAIR OF RIGHT RETINAL HORSESHOE TEAR' reason for change: Per Query Resolution                                                                                                                                                                              | (b) (4)                   | 15 Oct 2020 15:24:00 |
| User opened query 'Cryotherapy of right eye was done on 06Oct. Please add procedure to this eCRF. No source for Laser repair of right retial horsehoe tear done on 01Oct. Please provide to verify this procedure. ' (Site from CRA).                                                             | (b) (4), (b) (6)          | 14 Oct 2020 20:58:08 |
| User entered 'Laser REPAIR OF RIGHT RETINAL HORSESHOE TEAR' reason for change: Data Entry Error                                                                                                                                                                                                   | Heather Douds (b) (4)     | 02 Oct 2020 20:44:04 |
| User entered 'Repair of right retinal horseshoe tear'                                                                                                                                                                                                                                             | Heather Douds (b) (4)     | 02 Oct 2020 20:43:56 |

US3552140

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                             | User                             | Time (GMT)           |
|-----------------------------------|----------------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)                 | 28 Oct 2020 15:26:20 |
| User entered 'Adverse Event (AE)' | Heather Douds (b) (4)<br>(b) (4) | 02 Oct 2020 20:43:56 |

US3552140

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 09:35:57**

[If indication is Other, specify](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 28 Oct 2020 15:26:20 |
| User entered empty. | Heather Douds (b) (4)<br>(b) (4) | 02 Oct 2020 20:43:56 |

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:35:57

Procedure/Surgery date (dd MMM yyyy)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 28 Oct 2020 15:26:20 |
| User entered '06 Oct 2020' reason for change: Data Entry Error | Cassandra Zehenny (b) (4) | 15 Oct 2020 15:25:48 |
| DataPoint Un-verified.                                         | (b) (4)                   |                      |
|                                                                | Cassandra Zehenny (b) (4) | 15 Oct 2020 15:22:47 |
| User entered '01 Oct 2020' reason for change: Data Entry Error | (b) (4)                   |                      |
|                                                                | Cassandra Zehenny (b) (4) | 15 Oct 2020 15:22:47 |
| DataPoint Verified.                                            | (b) (4)                   |                      |
|                                                                | (b) (4), (b) (6)          | 14 Oct 2020 20:47:35 |
| User entered '9 Oct 2020'                                      | Joan Siegner (b) (4)      | 12 Oct 2020 17:05:20 |
|                                                                |                           |                      |
|                                                                |                           |                      |

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:35:57

[Procedure/Surgery](#)

| Audit                                                                       | User                      | Time (GMT)           |
|-----------------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                         | (b) (4), (b) (6)          | 28 Oct 2020 15:26:20 |
| DataPoint Un-verified.                                                      | Cassandra Zehenny (b) (4) | 15 Oct 2020 15:25:48 |
| User entered 'Cryotherapy of right eye' reason for change: Data Entry Error | (b) (4)                   |                      |
|                                                                             | Cassandra Zehenny (b) (4) | 15 Oct 2020 15:25:48 |
| DataPoint Verified.                                                         | (b) (4)                   |                      |
|                                                                             | (b) (4), (b) (6)          | 14 Oct 2020 20:47:36 |
| User entered 'laser photocoagulation right eye'                             | Joan Siegner (b) (4)      | 12 Oct 2020 17:05:20 |
|                                                                             |                           |                      |
|                                                                             |                           |                      |

US3552140

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 26 Nov 2020 09:35:57**

[Indication](#)

| Audit                             | User                 | Time (GMT)           |
|-----------------------------------|----------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)     | 14 Oct 2020 20:47:38 |
| User entered 'Adverse Event (AE)' | Joan Siegner (b) (4) | 12 Oct 2020 17:05:20 |

US3552140

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 26 Nov 2020 09:35:57**

[If indication is Other, specify](#)

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)     | 14 Oct 2020 20:47:39 |
| User entered empty. | Joan Siegner (b) (4) | 12 Oct 2020 17:05:20 |

US3552140

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 26 Nov 2020 09:35:57**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                   | 09 Nov 2020 15:40:45 |
| User entered '21 Sep 2020' | Stanley Doublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:32:43 |

US3552140

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 26 Nov 2020 09:35:57**

[Primary reason for dosing discontinuation](#)

| Audit                                                                              | User                               | Time (GMT)           |
|------------------------------------------------------------------------------------|------------------------------------|----------------------|
| DataPoint Verified.                                                                | (b) (4), (b) (6)                   | 09 Nov 2020 15:40:45 |
| User entered 'AE (specify) (ADVERSE EVENT)'<br>reason for change: Data Entry Error | Heather Douds (b) (4)<br>(b) (4)   | 20 Oct 2020 14:18:20 |
| User entered 'Physician decision (specify)<br>(PHYSICIAN DECISION)'                | Stanley Doublin (b) (4)<br>(b) (4) | 21 Sep 2020 16:32:43 |

US3552140

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:35:57

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

| Audit                                                                                                                                                                                                                                                  | User                      | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM). DataPoint Verified.                                                                                                                                    | (b) (4), (b) (6)          | 22 Nov 2020 23:32:08 |
|                                                                                                                                                                                                                                                        | (b) (4), (b) (6)          | 19 Nov 2020 19:48:39 |
| User closed query 'Please change to AE # 2 ( actual line # for AE retinal detachment). ' (Site from CRA). Query 'Please change to AE # 2 ( actual line # for AE retinal detachment). ' answered with 'updated' (Site from CRA). DataPoint Un-verified. | (b) (4), (b) (6)          | 19 Nov 2020 19:48:28 |
|                                                                                                                                                                                                                                                        | Heather Douds (b) (4)     | 19 Nov 2020 19:11:43 |
|                                                                                                                                                                                                                                                        | (b) (4)                   |                      |
|                                                                                                                                                                                                                                                        | Heather Douds (b) (4)     | 19 Nov 2020 19:11:38 |
|                                                                                                                                                                                                                                                        | (b) (4)                   |                      |
| User entered 'AE #2' reason for change: Per Query Resolution                                                                                                                                                                                           | Heather Douds (b) (4)     | 19 Nov 2020 19:11:38 |
|                                                                                                                                                                                                                                                        | (b) (4)                   |                      |
| User opened query 'Please change to AE # 2 ( actual line # for AE retinal detachment). ' (Site from CRA).                                                                                                                                              | (b) (4), (b) (6)          | 19 Nov 2020 15:42:00 |
|                                                                                                                                                                                                                                                        | (b) (4), (b) (6)          |                      |
| Query 'Please enter SAE # USA-US089-2020-MRNA-1273-P301000002' canceled (Site from CRA).                                                                                                                                                               | (b) (4), (b) (6)          | 19 Nov 2020 14:21:19 |
|                                                                                                                                                                                                                                                        | (b) (4), (b) (6)          |                      |
| User opened query 'Please enter SAE # USA-US089-2020-MRNA-1273-P301000002' (Site from CRA).                                                                                                                                                            | (b) (4), (b) (6)          | 19 Nov 2020 01:51:20 |
|                                                                                                                                                                                                                                                        | (b) (4), (b) (6)          |                      |
| DataPoint Verified.                                                                                                                                                                                                                                    | (b) (4), (b) (6)          | 18 Nov 2020 20:07:12 |
|                                                                                                                                                                                                                                                        | (b) (4)                   |                      |
| Query 'Per CDM: Please record AE record number instead of details ' answered with 'updated' (Site from DM).                                                                                                                                            | Cassandra Zehenny (b) (4) | 18 Nov 2020 17:34:53 |
|                                                                                                                                                                                                                                                        | (b) (4)                   |                      |
| DataPoint Un-verified.                                                                                                                                                                                                                                 | Cassandra Zehenny (b) (4) | 18 Nov 2020 17:34:48 |
|                                                                                                                                                                                                                                                        | (b) (4)                   |                      |
| User entered 'AE #1' reason for change: Per Query Resolution                                                                                                                                                                                           | Cassandra Zehenny (b) (4) | 18 Nov 2020 17:34:48 |
|                                                                                                                                                                                                                                                        | (b) (4)                   |                      |
| User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).                                                                                                                                                        | (b) (4), (b) (6)          | 18 Nov 2020 16:15:47 |
|                                                                                                                                                                                                                                                        | (b) (4), (b) (6)          |                      |
| DataPoint Verified.                                                                                                                                                                                                                                    | (b) (4), (b) (6)          | 09 Nov 2020 15:40:45 |
|                                                                                                                                                                                                                                                        | (b) (4), (b) (6)          |                      |
| User closed query 'Please remove "AE#1" to state only the AE term (RETINAL DETACHMENT SURGERY) ' (Site from CRA).                                                                                                                                      | (b) (4), (b) (6)          | 24 Oct 2020 23:22:16 |
|                                                                                                                                                                                                                                                        | (b) (4)                   |                      |
| Query 'Please remove "AE#1" to state only the AE term (RETINAL DETACHMENT SURGERY) ' answered with 'Updated per query request' (Site from CRA).                                                                                                        | Cassandra Zehenny (b) (4) | 20 Oct 2020 16:26:16 |
|                                                                                                                                                                                                                                                        | (b) (4)                   |                      |

US3552140

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 26 Nov 2020 09:35:57**

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

| Audit                                                                                                            | User                      | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| User entered 'RETINAL DETACHMENT SURGERY' reason for change: Per Query Resolution                                | Cassandra Zehenny (b) (4) | 20 Oct 2020 16:26:10 |
| User opened query 'Please remove "AE#1" to state only the AE term (RETINAL DETACHMENT SURGERY)' (Site from CRA). | (b) (4), (b) (6)          | 20 Oct 2020 15:39:24 |
| User entered 'AE #1 RETINAL DETACHMENT SURGERY' reason for change: Data Entry Error                              | Heather Douds (b) (4)     | 20 Oct 2020 14:18:20 |
| User entered 'still recovering from recent retinal detachment surgery'                                           | Stanley Doublin (b) (4)   | 21 Sep 2020 16:32:43 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 08 Oct 2020 18:14:14 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered<br>'USA-US089-2020-MRNA-1273-P301000002' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 08 Oct 2020 18:14:16 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'Yes (Y)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:18 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:20 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:22 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:24 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:28 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 08 Oct 2020 18:14:30 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'Yes (Y)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's First Name](#)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6) | 08 Oct 2020 18:14:34 |
| Reviewed for Safety.                     | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'sharon' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's Last Name](#)

| Audit                                  | User             | Time (GMT)           |
|----------------------------------------|------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6) | 08 Oct 2020 18:14:37 |
| Reviewed for Safety.                   | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'frey' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: Street

| Audit                                                                  | User                      | Time (GMT)           |
|------------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 24 Nov 2020 18:33:03 |
| DataPoint Un-verified.                                                 | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                                    | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 11 Nov 2020 14:29:40 |
| User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                                | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                                 | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                                    | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                                   | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 09 Nov 2020 17:30:05 |
| User entered '1100 S. Grand Blvd'                                      | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: City

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 18:33:04 |
| DataPoint Un-verified.                                         | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                            | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 11 Nov 2020 14:29:42 |
| User entered 'Saint Louis' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                        | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                         | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                            | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 09 Nov 2020 17:30:07 |
| User entered 'St. Louis'                                       | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: [State](#)

| Audit                                | User             | Time (GMT)           |
|--------------------------------------|------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6) | 08 Oct 2020 18:14:39 |
| Reviewed for Safety.                 | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'MO' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Site Address: Postal Code](#)

| Audit                                                    | User                      | Time (GMT)           |
|----------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 24 Nov 2020 18:33:06 |
| DataPoint Un-verified.                                   | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                      | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 11 Nov 2020 14:29:43 |
| User entered '63104' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                  | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                   | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                      | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 09 Nov 2020 17:30:08 |
| User entered '63104'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator Country](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 08 Oct 2020 18:14:40 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 02:20:46 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 13 Sep 2020 11:26:06 |
| User entered 'US' (non-conformant).              | System           | 11 Sep 2020 13:55:23 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 10 Nov 2020 14:54:18 |
| User entered '4' | System | 30 Oct 2020 12:16:06 |
| User entered '3' | System | 18 Sep 2020 15:42:15 |
| User entered '2' | System | 13 Sep 2020 11:26:18 |
| User entered '1' | System | 11 Sep 2020 13:55:23 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 08 Oct 2020 18:14:14 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered<br>'USA-US089-2020-MRNA-1273-P301000002' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 08 Oct 2020 18:14:16 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'Yes (Y)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:18 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:20 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:22 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:24 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:28 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 08 Oct 2020 18:14:30 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'Yes (Y)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's First Name](#)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6) | 08 Oct 2020 18:14:34 |
| Reviewed for Safety.                     | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'sharon' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's Last Name](#)

| Audit                                  | User             | Time (GMT)           |
|----------------------------------------|------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6) | 08 Oct 2020 18:14:37 |
| Reviewed for Safety.                   | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'frey' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: Street

| Audit                                                                  | User                      | Time (GMT)           |
|------------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 24 Nov 2020 18:33:03 |
| DataPoint Un-verified.                                                 | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                                    | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 11 Nov 2020 14:29:40 |
| User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                                | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                                 | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                                    | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                                   | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 09 Nov 2020 17:30:05 |
| User entered '1100 S. Grand Blvd'                                      | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: City

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 18:33:04 |
| DataPoint Un-verified.                                         | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                            | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 11 Nov 2020 14:29:42 |
| User entered 'Saint Louis' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                        | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                         | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                            | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 09 Nov 2020 17:30:07 |
| User entered 'St. Louis'                                       | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: [State](#)

| Audit                                | User             | Time (GMT)           |
|--------------------------------------|------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6) | 08 Oct 2020 18:14:39 |
| Reviewed for Safety.                 | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'MO' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Site Address: Postal Code](#)

| Audit                                                    | User                      | Time (GMT)           |
|----------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 24 Nov 2020 18:33:06 |
| DataPoint Un-verified.                                   | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                      | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 11 Nov 2020 14:29:43 |
| User entered '63104' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                  | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                   | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                      | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 09 Nov 2020 17:30:08 |
| User entered '63104'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator Country](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 08 Oct 2020 18:14:40 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 02:20:46 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 13 Sep 2020 11:26:06 |
| User entered 'US' (non-conformant).              | System           | 11 Sep 2020 13:55:23 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 10 Nov 2020 14:54:18 |
| User entered '4' | System | 30 Oct 2020 12:16:06 |
| User entered '3' | System | 18 Sep 2020 15:42:15 |
| User entered '2' | System | 13 Sep 2020 11:26:18 |
| User entered '1' | System | 11 Sep 2020 13:55:23 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:35:57

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 05 Nov 2020 20:55:22 |
| User entered '11/Sep/2020 09:55' | System           | 11 Sep 2020 13:55:23 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:35:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 05 Nov 2020 20:55:24 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Sep 2020 11:26:06 |
| User entered '1'     | (b) (4), (b) (6) | 11 Sep 2020 13:55:23 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 08 Oct 2020 18:14:14 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered<br>'USA-US089-2020-MRNA-1273-P301000002' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 08 Oct 2020 18:14:16 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'Yes (Y)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:18 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:20 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:22 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:24 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:28 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 08 Oct 2020 18:14:30 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'Yes (Y)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's First Name](#)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6) | 08 Oct 2020 18:14:34 |
| Reviewed for Safety.                     | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'sharon' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's Last Name](#)

| Audit                                  | User             | Time (GMT)           |
|----------------------------------------|------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6) | 08 Oct 2020 18:14:37 |
| Reviewed for Safety.                   | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'frey' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: Street

| Audit                                                                  | User                      | Time (GMT)           |
|------------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 24 Nov 2020 18:33:03 |
| DataPoint Un-verified.                                                 | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                                    | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 11 Nov 2020 14:29:40 |
| User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                                | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                                 | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                                    | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                                   | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 09 Nov 2020 17:30:05 |
| User entered '1100 S. Grand Blvd'                                      | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: City

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 18:33:04 |
| DataPoint Un-verified.                                         | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                            | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 11 Nov 2020 14:29:42 |
| User entered 'Saint Louis' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                        | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                         | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                            | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 09 Nov 2020 17:30:07 |
| User entered 'St. Louis'                                       | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Site Address: State](#)

| Audit                                | User             | Time (GMT)           |
|--------------------------------------|------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6) | 08 Oct 2020 18:14:39 |
| Reviewed for Safety.                 | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'MO' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Site Address: Postal Code](#)

| Audit                                                    | User                      | Time (GMT)           |
|----------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 24 Nov 2020 18:33:06 |
| DataPoint Un-verified.                                   | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                      | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 11 Nov 2020 14:29:43 |
| User entered '63104' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                  | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                   | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                      | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 09 Nov 2020 17:30:08 |
| User entered '63104'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator Country](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 08 Oct 2020 18:14:40 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 02:20:46 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 13 Sep 2020 11:26:06 |
| User entered 'US' (non-conformant).              | System           | 11 Sep 2020 13:55:23 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 10 Nov 2020 14:54:18 |
| User entered '4' | System | 30 Oct 2020 12:16:06 |
| User entered '3' | System | 18 Sep 2020 15:42:15 |
| User entered '2' | System | 13 Sep 2020 11:26:18 |
| User entered '1' | System | 11 Sep 2020 13:55:23 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:35:57

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 05 Nov 2020 20:55:27 |
| User entered '13/Sep/2020 07:26' | System           | 13 Sep 2020 11:26:18 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:35:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 05 Nov 2020 20:55:29 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| User entered '1'     | (b) (4), (b) (6) | 13 Sep 2020 11:26:18 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 08 Oct 2020 18:14:14 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered<br>'USA-US089-2020-MRNA-1273-P301000002' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 08 Oct 2020 18:14:16 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'Yes (Y)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:18 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:20 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:22 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:24 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:28 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 08 Oct 2020 18:14:30 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'Yes (Y)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's First Name](#)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6) | 08 Oct 2020 18:14:34 |
| Reviewed for Safety.                     | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'sharon' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's Last Name](#)

| Audit                                  | User             | Time (GMT)           |
|----------------------------------------|------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6) | 08 Oct 2020 18:14:37 |
| Reviewed for Safety.                   | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'frey' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: Street

| Audit                                                                  | User                      | Time (GMT)           |
|------------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 24 Nov 2020 18:33:03 |
| DataPoint Un-verified.                                                 | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                                    | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 11 Nov 2020 14:29:40 |
| User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                                | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                                 | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                                    | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                                   | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 09 Nov 2020 17:30:05 |
| User entered '1100 S. Grand Blvd'                                      | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: City

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 18:33:04 |
| DataPoint Un-verified.                                         | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                            | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 11 Nov 2020 14:29:42 |
| User entered 'Saint Louis' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                        | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                         | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                            | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 09 Nov 2020 17:30:07 |
| User entered 'St. Louis'                                       | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: [State](#)

| Audit                                | User             | Time (GMT)           |
|--------------------------------------|------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6) | 08 Oct 2020 18:14:39 |
| Reviewed for Safety.                 | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'MO' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Site Address: Postal Code](#)

| Audit                                                    | User                      | Time (GMT)           |
|----------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 24 Nov 2020 18:33:06 |
| DataPoint Un-verified.                                   | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                      | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 11 Nov 2020 14:29:43 |
| User entered '63104' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                  | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                   | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                      | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 09 Nov 2020 17:30:08 |
| User entered '63104'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator Country](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 08 Oct 2020 18:14:40 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 02:20:46 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 13 Sep 2020 11:26:06 |
| User entered 'US' (non-conformant).              | System           | 11 Sep 2020 13:55:23 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 10 Nov 2020 14:54:18 |
| User entered '4' | System | 30 Oct 2020 12:16:06 |
| User entered '3' | System | 18 Sep 2020 15:42:15 |
| User entered '2' | System | 13 Sep 2020 11:26:18 |
| User entered '1' | System | 11 Sep 2020 13:55:23 |

US3552140

**Folder:** SAE USA-US089-2020-MRNA-1273-P301000002

**Form:** Safety Report Form (3)

**Generated On:** 26 Nov 2020 09:35:57

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 05 Nov 2020 20:55:35 |
| User entered '18/Sep/2020 11:42' | System           | 18 Sep 2020 15:42:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:35:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 05 Nov 2020 20:55:37 |
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Oct 2020 12:15:58 |
| User entered '1'     | (b) (4), (b) (6) | 18 Sep 2020 15:42:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 08 Oct 2020 18:14:14 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered<br>'USA-US089-2020-MRNA-1273-P301000002' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 08 Oct 2020 18:14:16 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'Yes (Y)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:18 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:20 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:22 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:24 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:28 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 08 Oct 2020 18:14:30 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'Yes (Y)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's First Name](#)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6) | 08 Oct 2020 18:14:34 |
| Reviewed for Safety.                     | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'sharon' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's Last Name](#)

| Audit                                  | User             | Time (GMT)           |
|----------------------------------------|------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6) | 08 Oct 2020 18:14:37 |
| Reviewed for Safety.                   | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'frey' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: Street

| Audit                                                                  | User                      | Time (GMT)           |
|------------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 24 Nov 2020 18:33:03 |
| DataPoint Un-verified.                                                 | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                                    | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 11 Nov 2020 14:29:40 |
| User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                                | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                                 | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                                    | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                                   | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 09 Nov 2020 17:30:05 |
| User entered '1100 S. Grand Blvd'                                      | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: City

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 18:33:04 |
| DataPoint Un-verified.                                         | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                            | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 11 Nov 2020 14:29:42 |
| User entered 'Saint Louis' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                        | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                         | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                            | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 09 Nov 2020 17:30:07 |
| User entered 'St. Louis'                                       | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: [State](#)

| Audit                                | User             | Time (GMT)           |
|--------------------------------------|------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6) | 08 Oct 2020 18:14:39 |
| Reviewed for Safety.                 | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'MO' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Site Address: Postal Code](#)

| Audit                                                    | User                      | Time (GMT)           |
|----------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 24 Nov 2020 18:33:06 |
| DataPoint Un-verified.                                   | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                      | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 11 Nov 2020 14:29:43 |
| User entered '63104' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                  | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                   | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                      | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 09 Nov 2020 17:30:08 |
| User entered '63104'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator Country](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 08 Oct 2020 18:14:40 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 02:20:46 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 13 Sep 2020 11:26:06 |
| User entered 'US' (non-conformant).              | System           | 11 Sep 2020 13:55:23 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 10 Nov 2020 14:54:18 |
| User entered '4' | System | 30 Oct 2020 12:16:06 |
| User entered '3' | System | 18 Sep 2020 15:42:15 |
| User entered '2' | System | 13 Sep 2020 11:26:18 |
| User entered '1' | System | 11 Sep 2020 13:55:23 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:35:57

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 05 Nov 2020 20:55:41 |
| User entered '30/Oct/2020 08:16' | System           | 30 Oct 2020 12:16:06 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:35:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Nov 2020 14:53:59 |
|                      |                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6) | 05 Nov 2020 20:55:42 |
|                      |                  |                      |
| User entered '1'     | (b) (4), (b) (6) | 30 Oct 2020 12:16:06 |
|                      |                  |                      |
|                      |                  |                      |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 08 Oct 2020 18:14:14 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered<br>'USA-US089-2020-MRNA-1273-P301000002' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 08 Oct 2020 18:14:16 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'Yes (Y)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:18 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:20 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:22 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:24 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 08 Oct 2020 18:14:28 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'No (N)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 08 Oct 2020 18:14:30 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 11 Sep 2020 13:55:14 |
| User entered 'Yes (Y)' | System           | 11 Sep 2020 13:53:03 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's First Name](#)

| Audit                                    | User             | Time (GMT)           |
|------------------------------------------|------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6) | 08 Oct 2020 18:14:34 |
| Reviewed for Safety.                     | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'sharon' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's Last Name](#)

| Audit                                  | User             | Time (GMT)           |
|----------------------------------------|------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6) | 08 Oct 2020 18:14:37 |
| Reviewed for Safety.                   | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'frey' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: [Street](#)

| Audit                                                                  | User                      | Time (GMT)           |
|------------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 24 Nov 2020 18:33:03 |
| DataPoint Un-verified.                                                 | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                                    | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 11 Nov 2020 14:29:40 |
| User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                                | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                                 | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                                    | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                                   | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 09 Nov 2020 17:30:05 |
| User entered '1100 S. Grand Blvd'                                      | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: City

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 18:33:04 |
| DataPoint Un-verified.                                         | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                            | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 11 Nov 2020 14:29:42 |
| User entered 'Saint Louis' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                        | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                         | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                            | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 09 Nov 2020 17:30:07 |
| User entered 'St. Louis'                                       | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: [State](#)

| Audit                                | User             | Time (GMT)           |
|--------------------------------------|------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6) | 08 Oct 2020 18:14:39 |
| Reviewed for Safety.                 | (b) (4), (b) (6) | 18 Sep 2020 15:42:00 |
| Amendment Manager: User entered 'MO' | System           | 14 Sep 2020 22:06:36 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Site Address: Postal Code](#)

| Audit                                                    | User                      | Time (GMT)           |
|----------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 24 Nov 2020 18:33:06 |
| DataPoint Un-verified.                                   | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                      | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 11 Nov 2020 14:29:43 |
| User entered '63104' reason for change: Data Entry Error | Heather Douds (b) (4)     | 11 Nov 2020 14:21:23 |
| Un-reviewed for Safety.                                  | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Un-verified.                                   | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                      | System                    | 10 Nov 2020 14:54:18 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 10 Nov 2020 14:53:59 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 09 Nov 2020 17:30:08 |
| User entered '63104'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:33:55 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator Country](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 08 Oct 2020 18:14:40 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 02:20:46 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 13 Sep 2020 11:26:06 |
| User entered 'US' (non-conformant).              | System           | 11 Sep 2020 13:55:23 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 10 Nov 2020 14:54:18 |
| User entered '4' | System | 30 Oct 2020 12:16:06 |
| User entered '3' | System | 18 Sep 2020 15:42:15 |
| User entered '2' | System | 13 Sep 2020 11:26:18 |
| User entered '1' | System | 11 Sep 2020 13:55:23 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:35:57

Date of submission (Pre-filled from custom function)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 11 Nov 2020 14:04:42 |
| User entered '10/Nov/2020 09:54' | System           | 10 Nov 2020 14:54:18 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:35:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 14:04:43 |
| User entered '1'    | (b) (4), (b) (6) | 10 Nov 2020 14:54:18 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 30 Oct 2020 15:47:06 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered<br>'USA-US089-2020-MRNA-1273-P301000007' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 30 Oct 2020 15:47:08 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:09 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:12 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:13 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:15 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 30 Oct 2020 15:47:17 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's First Name](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:18 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'sharon' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's Last Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'frey'  | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: Street

| Audit                                                                 | User                      | Time (GMT)           |
|-----------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 24 Nov 2020 18:33:38 |
| Un-reviewed for Safety.                                               | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                                | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                                   | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                                  | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 12 Nov 2020 13:34:58 |
| Un-reviewed for Safety.                                               | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered '1100 S. Grand Blvd' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                                  | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                                | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                                   | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 09 Nov 2020 17:32:21 |
| User entered '1100 S. Grand Blvd'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: City

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 18:33:39 |
| Un-reviewed for Safety.                                        | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                         | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                            | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 12 Nov 2020 13:34:59 |
| Un-reviewed for Safety.                                        | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered 'Saint Louis' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                         | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                            | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 09 Nov 2020 17:32:23 |
| User entered 'St. Louis'                                       | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Site Address: State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'MO'    | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: [Postal Code](#)

| Audit                                                    | User                      | Time (GMT)           |
|----------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 24 Nov 2020 18:33:36 |
| Un-reviewed for Safety.                                  | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                   | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                      | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 12 Nov 2020 13:35:01 |
| Un-reviewed for Safety.                                  | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered '63104' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                   | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                      | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 09 Nov 2020 17:32:24 |
| User entered '63104'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:23 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Oct 2020 16:45:34 |
| User entered 'US'    | System           | 05 Oct 2020 13:26:35 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 24 Nov 2020 13:19:32 |
| User entered '4' | System | 10 Nov 2020 14:54:41 |
| User entered '3' | System | 29 Oct 2020 12:26:12 |
| User entered '2' | System | 13 Oct 2020 16:45:44 |
| User entered '1' | System | 05 Oct 2020 13:26:35 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 30 Oct 2020 15:47:06 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered<br>'USA-US089-2020-MRNA-1273-P301000007' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 30 Oct 2020 15:47:08 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:09 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:12 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:13 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:15 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 30 Oct 2020 15:47:17 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's First Name](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:18 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'sharon' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's Last Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'frey'  | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: Street

| Audit                                                                 | User                      | Time (GMT)           |
|-----------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 24 Nov 2020 18:33:38 |
| Un-reviewed for Safety.                                               | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                                | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                                   | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                                  | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 12 Nov 2020 13:34:58 |
| Un-reviewed for Safety.                                               | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered '1100 S. Grand Blvd' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                                  | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                                | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                                   | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 09 Nov 2020 17:32:21 |
| User entered '1100 S. Grand Blvd'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: City

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 18:33:39 |
| Un-reviewed for Safety.                                        | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                         | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                            | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 12 Nov 2020 13:34:59 |
| Un-reviewed for Safety.                                        | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered 'Saint Louis' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                         | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                            | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 09 Nov 2020 17:32:23 |
| User entered 'St. Louis'                                       | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: [State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'MO'    | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: [Postal Code](#)

| Audit                                                    | User                      | Time (GMT)           |
|----------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 24 Nov 2020 18:33:36 |
| Un-reviewed for Safety.                                  | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                   | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                      | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 12 Nov 2020 13:35:01 |
| Un-reviewed for Safety.                                  | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered '63104' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                   | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                      | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 09 Nov 2020 17:32:24 |
| User entered '63104'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:23 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Oct 2020 16:45:34 |
| User entered 'US'    | System           | 05 Oct 2020 13:26:35 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 24 Nov 2020 13:19:32 |
| User entered '4' | System | 10 Nov 2020 14:54:41 |
| User entered '3' | System | 29 Oct 2020 12:26:12 |
| User entered '2' | System | 13 Oct 2020 16:45:44 |
| User entered '1' | System | 05 Oct 2020 13:26:35 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:35:57

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 05 Nov 2020 20:55:55 |
| User entered '05/Oct/2020 13:26' | System           | 05 Oct 2020 13:26:35 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:35:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 05 Nov 2020 20:55:57 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Oct 2020 16:45:34 |
| User entered '1'     | (b) (4), (b) (6) | 05 Oct 2020 13:26:35 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 30 Oct 2020 15:47:06 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered<br>'USA-US089-2020-MRNA-1273-P301000007' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 30 Oct 2020 15:47:08 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:09 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:12 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:13 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:15 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 30 Oct 2020 15:47:17 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's First Name](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:18 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'sharon' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's Last Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'frey'  | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: Street

| Audit                                                                 | User                      | Time (GMT)           |
|-----------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 24 Nov 2020 18:33:38 |
| Un-reviewed for Safety.                                               | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                                | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                                   | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                                  | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 12 Nov 2020 13:34:58 |
| Un-reviewed for Safety.                                               | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered '1100 S. Grand Blvd' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                                  | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                                | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                                   | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 09 Nov 2020 17:32:21 |
| User entered '1100 S. Grand Blvd'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: City

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 18:33:39 |
| Un-reviewed for Safety.                                        | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                         | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                            | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 12 Nov 2020 13:34:59 |
| Un-reviewed for Safety.                                        | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered 'Saint Louis' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                         | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                            | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 09 Nov 2020 17:32:23 |
| User entered 'St. Louis'                                       | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Site Address: State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'MO'    | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: [Postal Code](#)

| Audit                                                    | User                      | Time (GMT)           |
|----------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 24 Nov 2020 18:33:36 |
| Un-reviewed for Safety.                                  | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                   | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                      | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 12 Nov 2020 13:35:01 |
| Un-reviewed for Safety.                                  | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered '63104' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                   | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                      | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 09 Nov 2020 17:32:24 |
| User entered '63104'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:23 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Oct 2020 16:45:34 |
| User entered 'US'    | System           | 05 Oct 2020 13:26:35 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 24 Nov 2020 13:19:32 |
| User entered '4' | System | 10 Nov 2020 14:54:41 |
| User entered '3' | System | 29 Oct 2020 12:26:12 |
| User entered '2' | System | 13 Oct 2020 16:45:44 |
| User entered '1' | System | 05 Oct 2020 13:26:35 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:35:57

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 05 Nov 2020 20:56:00 |
| User entered '13/Oct/2020 16:45' | System           | 13 Oct 2020 16:45:44 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:35:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 05 Nov 2020 20:56:02 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 12:26:03 |
| User entered '1'     | (b) (4), (b) (6) | 13 Oct 2020 16:45:44 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 30 Oct 2020 15:47:06 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered<br>'USA-US089-2020-MRNA-1273-P301000007' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 30 Oct 2020 15:47:08 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:09 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:12 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:13 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:15 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 30 Oct 2020 15:47:17 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's First Name](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:18 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'sharon' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's Last Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'frey'  | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: Street

| Audit                                                                 | User                      | Time (GMT)           |
|-----------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 24 Nov 2020 18:33:38 |
| Un-reviewed for Safety.                                               | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                                | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                                   | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                                  | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 12 Nov 2020 13:34:58 |
| Un-reviewed for Safety.                                               | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered '1100 S. Grand Blvd' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                                  | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                                | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                                   | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 09 Nov 2020 17:32:21 |
| User entered '1100 S. Grand Blvd'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: City

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 18:33:39 |
| Un-reviewed for Safety.                                        | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                         | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                            | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 12 Nov 2020 13:34:59 |
| Un-reviewed for Safety.                                        | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered 'Saint Louis' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                         | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                            | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 09 Nov 2020 17:32:23 |
| User entered 'St. Louis'                                       | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: [State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'MO'    | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: [Postal Code](#)

| Audit                                                    | User                      | Time (GMT)           |
|----------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 24 Nov 2020 18:33:36 |
| Un-reviewed for Safety.                                  | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                   | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                      | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 12 Nov 2020 13:35:01 |
| Un-reviewed for Safety.                                  | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered '63104' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                   | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                      | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 09 Nov 2020 17:32:24 |
| User entered '63104'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:23 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Oct 2020 16:45:34 |
| User entered 'US'    | System           | 05 Oct 2020 13:26:35 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 24 Nov 2020 13:19:32 |
| User entered '4' | System | 10 Nov 2020 14:54:41 |
| User entered '3' | System | 29 Oct 2020 12:26:12 |
| User entered '2' | System | 13 Oct 2020 16:45:44 |
| User entered '1' | System | 05 Oct 2020 13:26:35 |

US3552140

**Folder:** SAE USA-US089-2020-MRNA-1273-P301000007

**Form:** Safety Report Form (3)

**Generated On:** 26 Nov 2020 09:35:57

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 05 Nov 2020 20:56:07 |
| User entered '29/Oct/2020 08:26' | System           | 29 Oct 2020 12:26:12 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:35:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Nov 2020 14:54:26 |
|                      |                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6) | 05 Nov 2020 20:56:10 |
|                      |                  |                      |
| User entered '1'     | (b) (4), (b) (6) | 29 Oct 2020 12:26:12 |
|                      |                  |                      |
|                      |                  |                      |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 30 Oct 2020 15:47:06 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered<br>'USA-US089-2020-MRNA-1273-P301000007' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 30 Oct 2020 15:47:08 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:09 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:12 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:13 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:15 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 30 Oct 2020 15:47:17 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's First Name](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:18 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'sharon' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's Last Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'frey'  | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: Street

| Audit                                                                 | User                      | Time (GMT)           |
|-----------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 24 Nov 2020 18:33:38 |
| Un-reviewed for Safety.                                               | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                                | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                                   | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                                  | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 12 Nov 2020 13:34:58 |
| Un-reviewed for Safety.                                               | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered '1100 S. Grand Blvd' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                                  | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                                | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                                   | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 09 Nov 2020 17:32:21 |
| User entered '1100 S. Grand Blvd'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: City

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 18:33:39 |
| Un-reviewed for Safety.                                        | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                         | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                            | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 12 Nov 2020 13:34:59 |
| Un-reviewed for Safety.                                        | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered 'Saint Louis' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                         | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                            | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 09 Nov 2020 17:32:23 |
| User entered 'St. Louis'                                       | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: [State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'MO'    | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: [Postal Code](#)

| Audit                                                    | User                      | Time (GMT)           |
|----------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 24 Nov 2020 18:33:36 |
| Un-reviewed for Safety.                                  | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                   | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                      | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 12 Nov 2020 13:35:01 |
| Un-reviewed for Safety.                                  | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered '63104' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                   | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                      | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 09 Nov 2020 17:32:24 |
| User entered '63104'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:23 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Oct 2020 16:45:34 |
| User entered 'US'    | System           | 05 Oct 2020 13:26:35 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 24 Nov 2020 13:19:32 |
| User entered '4' | System | 10 Nov 2020 14:54:41 |
| User entered '3' | System | 29 Oct 2020 12:26:12 |
| User entered '2' | System | 13 Oct 2020 16:45:44 |
| User entered '1' | System | 05 Oct 2020 13:26:35 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:35:57

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 12 Nov 2020 01:59:00 |
| User entered '10/Nov/2020 09:54' | System           | 10 Nov 2020 14:54:41 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:35:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 13:19:20 |
| DataPoint Verified.  | (b) (4), (b) (6) | 12 Nov 2020 01:59:02 |
| User entered '1'     | (b) (4), (b) (6) | 10 Nov 2020 14:54:41 |
|                      |                  |                      |
|                      |                  |                      |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 30 Oct 2020 15:47:06 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered<br>'USA-US089-2020-MRNA-1273-P301000007' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Serious

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 30 Oct 2020 15:47:08 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:09 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:11 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:12 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:13 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:15 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'No (N)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Other medically important event](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 30 Oct 2020 15:47:17 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'Yes (Y)' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's First Name](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 30 Oct 2020 15:47:18 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'sharon' | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator's Last Name](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:20 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'frey'  | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: Street

| Audit                                                                 | User                      | Time (GMT)           |
|-----------------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 24 Nov 2020 18:33:38 |
| Un-reviewed for Safety.                                               | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                                | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                                   | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                                  | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 12 Nov 2020 13:34:58 |
| Un-reviewed for Safety.                                               | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered '1100 S. Grand Blvd' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                                  | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                                | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                                   | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                                   | (b) (4), (b) (6)          | 09 Nov 2020 17:32:21 |
| User entered '1100 S. Grand Blvd'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: City

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 18:33:39 |
| Un-reviewed for Safety.                                        | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                         | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                            | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 12 Nov 2020 13:34:59 |
| Un-reviewed for Safety.                                        | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered 'Saint Louis' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                           | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                         | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                            | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 09 Nov 2020 17:32:23 |
| User entered 'St. Louis'                                       | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: [State](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:22 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Oct 2020 12:57:30 |
| User entered 'MO'    | System           | 05 Oct 2020 12:56:51 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

Site Address: [Postal Code](#)

| Audit                                                    | User                      | Time (GMT)           |
|----------------------------------------------------------|---------------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 24 Nov 2020 18:33:36 |
| Un-reviewed for Safety.                                  | System                    | 24 Nov 2020 13:19:32 |
| DataPoint Un-verified.                                   | System                    | 24 Nov 2020 13:19:32 |
| User entered empty.                                      | System                    | 24 Nov 2020 13:19:32 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 24 Nov 2020 13:19:20 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 12 Nov 2020 13:35:01 |
| Un-reviewed for Safety.                                  | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| User entered '63104' reason for change: Data Entry Error | Heather Douds (b) (4)     | 12 Nov 2020 13:02:57 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)          | 10 Nov 2020 14:54:26 |
| DataPoint Un-verified.                                   | System                    | 10 Nov 2020 14:54:18 |
| User entered empty.                                      | System                    | 10 Nov 2020 14:54:18 |
| DataPoint Verified.                                      | (b) (4), (b) (6)          | 09 Nov 2020 17:32:24 |
| User entered '63104'                                     | Cassandra Zehenny (b) (4) | 09 Nov 2020 16:34:15 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[Investigator Country](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 30 Oct 2020 15:47:23 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Oct 2020 16:45:34 |
| User entered 'US'    | System           | 05 Oct 2020 13:26:35 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:35:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 24 Nov 2020 13:19:32 |
| User entered '4' | System | 10 Nov 2020 14:54:41 |
| User entered '3' | System | 29 Oct 2020 12:26:12 |
| User entered '2' | System | 13 Oct 2020 16:45:44 |
| User entered '1' | System | 05 Oct 2020 13:26:35 |

**US3552140**

**Folder: SAE USA-US089-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (5)**

**Generated On: 26 Nov 2020 09:35:57**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 24 Nov 2020 18:33:57 |
| User entered '24/Nov/2020 13:19' | System           | 24 Nov 2020 13:19:32 |

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:35:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 18:33:59 |
| User entered '1'    | (b) (4), (b) (6) | 24 Nov 2020 13:19:32 |